LPT Report No. 38166
Amendment No. 1 to Final Report

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

(Final Report dated 01 July 2020)

Sponsor:
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Study conducted by:
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17 September 2020

This Amendment No. 1 to Final Report consists of 2233 pages and 4 pages.
This is page I.

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REASONS FOR AMENDMENT NO. 1 TO FINAL REPORT

Upon request of the Sponsor, minor layout changes and/or corrections are made to the report that do not affect the validity and scientific results or the conclusions of the final report.

The following changes were made:

1. SUMMARY - FINDINGS

To improve readability and provide a more comprehensive summary, all Text tables are deleted from Section 1.2 and replaced with references to the respective Text tables in the results section of the report.

Furthermore, in Section 1.2 in the paragraph on local tolerance the finding of eschar formation was incorrectly described with occurrence on test days 14 and 15 instead of on test day 14 only. Additionally, in the paragraph on haematology and coagulation the finding of an increased number of eosinophils in groups 4, 5 and 7 was missing. Further, in the paragraph on clinical chemistry the directions of changes for albumin and globulin levels were incorrectly stated as an increase in albumin and a decrease in globulin plasma levels instead of a decrease in albumin and an increase in globulin plasma levels.

In this Amendment No. 1 to Final Report the incorrect finding of eschar formation and the incorrect directions of changes for albumin and globulin are corrected, and the finding of an increased number of eosinophils in groups 4, 5 and 7 is added.

2. TEST ITEM

In Section 2.3.5 on test item no. 5, the designation for the test item was incorrectly given as ‘modRNA’ instead of ‘saRNA’.

In this Amendment No. 1 to Final Report the incorrect designation is corrected.

3. RESULTS

In Section 4.7 the finding of an increased number of eosinophils in groups 4, 5 and 7 was missing. Additionally, in Section 4.8 the directions of change for albumin and globulin levels were incorrectly stated as an increase in albumin and a decrease in globulin plasma levels instead of a decrease in albumin and an increase in globulin plasma levels.

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In this Amendment No. 1 to Final Report the incorrect directions of changes for albumin and globulin are corrected, and the finding of an increased number of eosinophils in groups 4, 5 and 7 is added.

4. TABLES

In Table 1-2 (Local Tolerance - Erythema, Oedema, Induration, Hardening) the incorrect test item 'BNT162b1' instead of 'BNT162a1' was stated for Group 3. In addition, the grading scale as given in the footnote was specific for erythema only, and the gradings for oedema and indurations were missing.

In this Amendment No. 1 to Final Report the incorrect test item is corrected. The grading scale given in the footnote is referred to erythema, and additionally, for oedema and indurations the respective grading scales are given as a reference to Section 3.8.3.

5. ADDITIONAL CHANGES

In Section 4. 1, the main sentence of the last sentence of the second paragraph was missing the verb "was noted", which is now added to the text (i.e. "[...] was noted on test day 14 [...]").

The following typing errors in the Final Report are corrected by this Amendment No. 1 to Final Report:

Quality Assurance Statement: Year of the Study Plan '16 March 2020' instead of '16 March 2019'.

Section 4. 7: In Text table 4-9, for the parameter "eosinophils" the sex is corrected from 'm' to 'f'.

Section 4.8: In Text table 4-12, for the parameter "globulin" the entry 'Group: 4, Sex: m, Test day: 17, Change: + 9.5% * *' is corrected to 'Group: 4, Sex: f, Test day: 4, Change: + 9.5% *'.

This amendment does not affect the validity of the data.

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This Amendment No. 1 to Final Report has been audited by the Quality Assurance Unit (QAU) and is considered to be an accurate account of the project.

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STATEMENT OF COMPLIANCE

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

The study was performed in compliance with:

- 'Good Laboratory Practice' Regulations of the EC enacted in Germany in the 'Chemikaliengesetz' [Chemicals Act], current edition;
- 'OECD Principles of Good Laboratory Practice' Document No. 1 (ENV/MC/CHEM (98) 17) regulated in the Directive 2004/10/EC of the European Parliament and the Council of 11 February 2004.

These principles are compatible with 'Good Laboratory Practice' (GLP) regulations specified by regulatory authorities throughout the European Community, the United States (EPA and FDA) and Japan (MHLW, MAFF, and METI). Animal husbandry is performed in compliance with EU Welfare Standards (Directive 2010/63/EU).

Raw data obtained during the performance of the study are accurately reflected.

The analysis of dose exposure was conducted under the responsibility of the Sponsor and is excluded from this statement.

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QUALITY ASSURANCE STATEMENT

Based on a quality assurance review, it was concluded that this report accurately reflects the raw data for the study. Methods, procedures and observations are correctly and completely described in the report:

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

Study Plan dated 16 March 2020 and 9 Study Plan amendments.

Text table 1: Inspections of **LPT**'s QAU

Date of inspection	Criteria	Date of report to the Study Director and the Management
16 Mar 2020	Study Plan.	16 Mar 2020
17 Mar 2020	Sponsor's visit: Prearrangements for test item preparation, administration, body temperature, local tolerance, documentation.	17 Mar 2020
24 Mar 2020	Body weight, blood withdrawal and processing for cytokine determination, time points of blood withdrawal, labels, administration, body temperature, local tolerance, documentation.	24 Mar 2020
31 Mar 2020	Blood withdrawal and processing for cytokine determination, time points of blood withdrawal, labels, administration, body temperature, local tolerance, documentation.	31 Mar 2020
08 Apr 2020	Urine collection, blood withdrawal and processing for laboratory examinations and for dose exposure analysis, dissection, organ removal, organ weights, documentation.	08 Apr 2020
21 Apr 2020	Body temperature, administration, blood withdrawal and processing, kinetics, labels, local tolerance, documentation.	21 Apr 2020
23 Apr 2020	Blood withdrawal and processing for laboratory examinations, dose exposure analysis and cytokine analysis, animal sacrifice, dissection, organ removal, organ weights, bone marrow smears, documentation.	23 Apr 2020
26 June and 29 June to 01 July 2020	Final Report.	01 July 2020
15 and 17 Sep 2020	Amendment to Final Report.	17 Sep 2020

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In addition to the detailed study-based inspections, series of routine facility inspections were also conducted and reported to the Management.

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EXPLANATIONS AND ABBREVIATIONS

Symbols

[1 - n]	reference to footnotes in text
#(n)	reference to footnotes in text tables
( )	animal number in the tables section
%	per cent
!	refer to result comment at the end of the table
...n	inappropriate for statistics (number of individual data values is less than 3 or all values were below lowest level of quantification, e.g. for cytokines)
↑	increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls
↓	decrease relative to study control range, but % difference not quantifiable due to lacking concurrent controls

Letters and acronyms

% Diff	percent difference (from control group)
a.m.	ante meridiem
abs.	absolute
ANOVA	analysis of variance
approx.	approximately
b.w.	body weight
EC	European Commission
EPA	Environmental Protection Agency (USA)
EU	European Union
f	female
FDA	Food and Drug Administration (USA)
GLP	Good Laboratory Practice
i.e.	id est (that is)
i.m.	intramuscular
Inj.	injection
LLOQ	lower limit of quantification
LNP	lipid nanoparticles
LPT	Laboratory of Pharmacology and Toxicology GmbH & Co. KG
LUFA-ITL	Landwirtschaftliche Untersuchungs- und Forschungsanstalt, Institut für Tiergesundheit und Lebensmittelqualität
m	male
MAFF	Ministry of Agriculture, Forestry and Fisheries (Japan)
METI	Ministry of Economy, Trade and Industry (Japan)
MHLW	Ministry of Health, Labour and Welfare (Japan)
MS	main study
n, N	number (e.g. group size, sample size)
n/a	not applicable
ns	not statistically significant
OECD	Organization for Economic Co-Operation and Development
p.a.	post administration
p.m.	post meridiem
PBS	phosphate-buffered saline
PEG	polyethylene glycol
PrDs	predose

- Letters and acronyms continued on the next page -

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Letters and acronyms *(continued)*

QAU	Quality Assurance Unit
RBD	receptor-binding domain
rel.	relative
RNA	ribonucleic acid
mRNA	messenger RNA
uRNA	uridine mRNA
modRNA	nucleoside-modified mRNA
saRNA	self-amplifying mRNA
RP	recovery period
SA	satellite animals
SARS	severe acute respiratory syndrome
SARS-CoV	SARS coronavirus
SD	standard deviation
SOP	Standard Operating Procedure
TD	test day
TS	terminal sacrifice
TW	test week
USA	United States of America

Weights and measures

°C	degree Celsius
cm	centimetre
dL	decilitre
fL	femtolitre
fmol	femtomole
g	gram
h	hour
kg	kilogram
L	litre
mg	milligram
min	minute
µg	microgram
µL	microlitre
µmol	micromole
mL	millilitre
mm	millimetre
mmol	millimole
sec	second
U	unit

Measuring units

Body weight in g
Food intake in g/kg b.w./day
Absolute organ weights in g
Relative organ weights in g/kg b.w.
Relative urine volume in mL/kg b.w./24 h

Haematology / Coagulation

aPTT	activated partial thromboplastin time
Baso	basophilic granulocytes

- Haematology / Coagulation continued on the next page -

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Haematology / Coagulation *(continued)*

Eos	eosinophilic granulocytes
HCT	haematocrit
HGB	haemoglobin
LUC	large unclassified cells
Lym	lymphocytes
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
Mono	monocytes
MPC	mean platelet component
MPV	mean platelet (thrombocyte) volume
Neut	neutrophilic granulocytes
PDW	platelet distribution width
PLT	platelets
PT	prothrombin time
RBC	red blood cell count (= erythrocytes)
RDW	red cell distribution width
Reti	reticulocytes
WBC	white blood cell count (= leucocytes)

Clinical chemistry

Alb.	albumin
ALAT	alanine aminotransferase
aP	alkaline phosphatase
ASAT	aspartate aminotransferase
CK	creatine kinase
Glob.	globulin
Gamma-GT	gamma-glutamyltransferase
LDH	lactate dehydrogenase

Cytokines

IFN-gamma	interferon-alpha
IL-1beta	interleukin-1 beta
IL-6	interleukin-6
IL-10	interleukin-10
TNF-alpha	tumour necrosis factor-alpha

Urinalysis

+	'small amount' of analyte/few in some fields examined
+ +	'moderate amount' of analyte/few in all fields examined
+ + +	'large amount' of analyte/many in all fields examined
ery	erythrocyte
LC	lemon-coloured
neg	negative/none found in any field examined
pos	positive
SC	straw-coloured

Histopathology

For explanations see the 'Histopathological Report' in Section 6.

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Test item nomenclature

For reasons of better readability and due to space restrictions, the dose levels used in the study are referred to using the designations given below instead of the full designations as given in Section 2.3.

Group 2: **30 µg BNT162a1/animal**
Group 3: **10 µg BNT162a1/animal**
Group 4: **30 µg BNT162b1/animal**
Group 5: **100 µg BNT162b1/animal**
Group 6: **30 µg BNT162c1/animal**
Group 7: **100 µg BNT162b2/animal**

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1. SUMMARY

1.1 Conduct of study

Test items	1) BNT162a1 2) BNT162b1 3) BNT162b2 4) BNT162c1
Control item	Buffer (PBS/300 mM Sucrose)
Test item batch nos.	1) CoVVAC/090320 2) CoVVAC/100320 3) CoVVAC/160320 4) CoVVAC/130320
Control item batch no.	090320
Test species / Strain / Stock	Rat / Wistar / Crl:WI(Han)
Breeder	Charles River Laboratories, Research Models and Services, Germany GmbH Sandhofer Weg 7, 97633 Sulzfeld, Germany
Number and sex of animals	255 animals (126 + 3[1] males and 126 females)
Route of administration	Intramuscular (i.m.) administration into the Musculus biceps femoris using a Microfine+ Syringe 0.5 mL, 0.33 mm (29G) × 12.7 mm (BD, 324824).
Frequency of administration	Groups 1 to 5, and 7: On test days 1, 8 and 15; in total 3 administration days at one-week intervals per animal. Group 6: On test days 1 and 8; in total 2 administration days at a one-week interval per animal. Erroneously treated animals: Single dose on test day 1
Administration volume	Groups 1, 5, and 7: 100 µL/administration site; 2 administration sites In total 200 µL/animal/administration day Groups 2 and 4: 60 µL at one administration site In total 60 µL/animal/administration day

[1] Due to a short-term change of test item and dose level for group 3, three animals had already been treated with the originally planned test item and dose. These three animals were replaced by 3 spare animals for the correct teatment.

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	Group 3: 20 µL at one administration site In total 20 µL/animal/administration day Group 6: 70 µL at one administration site In total 70 µL/animal/administration day Erroneously treated animals: 100 µL/administration site; 2 administration sites In total 200 µL/animal/administration day
Dosages	Groups 1 to 7: Group 1: Control (200 µL Buffer/animal) Group 2: 30 µg BNT162a1/animal Group 3: 10 µg BNT162a1/animal Group 4: 30 µg BNT162b1/animal Group 5: 100 µg BNT162b1/animal Group 6: 30 µg BNT162c1/animal Group 7: 100 µg BNT162b2/animal Erroneously treated animals: 100 µg Test item 2 (BNT162a - 2)/animal
Duration of study	• 5 to 11 adaptation days • 17 test days for groups 1 to 5 and group 7 • 10 test days for group 6 • 3 additional weeks for the animals scheduled for the recovery period

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1.2 Findings

Local tolerance

Treatment period

Local reactions were observed in male and female animals treated intramuscularly with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8. The incidence and severity of the reactions were higher after the 2nd or 3rd injections compared with the 1st injection. The majority of animals revealed very slight to moderate oedema at the injection site(s) following the 1st, 2nd, and/or 3rd injection of the respective test item. A few animals had severe oedema at 48 h after the 2nd injection of **30 µg BNT162c1/animal** or 24 h after the 3rd injection of **100 µg BNT162b2/animal**. The majority of these observations of oedema were resolved or showed signs of resolution by 144 h postdose.

For a few animals, slight or well-defined erythema was also observed in test-item administered animals after the 1st, 2nd, and/or 3rd injection. In addition, after the 2nd or 3rd injection, transient observations of severe erythema were seen in all test article-dosed groups, except for **30 µg BNT162b1/animal**, starting at 96 h after administration. Occasionally these observations of severe erythema continued over several days and/or were associated with wounds or scar tissue in individual animals administered **30 µg BNT162a1/animal** or **30 µg BNT162c1/animal**.

On test day 14, eschar formation was observed at the injection site for 5 male and 6 female animals treated with **30 µg BNT162a1/animal**, which resulted in the decision to move the dosing site to the contralateral limb in 6 animals on test day 15.

The injection site appeared to be painful for 4 of 15 male animals and 12 of 15 female animals treated with **30 µg BNT162a1/animal** on test day 9 and for one male animal also on test day 10.

An indurated and/or thickened injection site, partly accompanied by incrustation, was noted for nearly all animals in all treatment groups at macroscopic inspection at necropsy.

The microscopic examination revealed that test item-related injection site reactions were present in all groups and characterized by mostly moderate inflammation (up to marked) in males

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and moderate inflammation in females. The most severe findings were consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate oedema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac).

Microscopic injection site findings correlated with macroscopic observations of thickening, induration, and incrustation. Injection site findings were consistent with an immune/inflammatory response to intramuscular vaccine administration.

Recovery period

The local skin reactions and the indurations and/or thickenings noted macroscopically for the muscle at the injection site(s) were resolved at the end of the recovery period.

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland, and skeletal muscle) partially or fully recovered at the end of the 3-week recovery period. Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals.

Clinical signs

Treatment and recovery period

None of the male and female animals treated intramuscularly with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal** or **100 µg BNT162b2/animal** on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** on test days 1 and 8 (2 administrations) revealed any test item-related systemic changes in

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behaviour, external appearance, or consistency of faeces.

Mortality

BNT162a1, BNT162b1, BNT162b2, BNT162c1
Treatment and recovery period
No test item-related deaths were noted for any treatment.

Body weight and body weight gain

BNT162a1, BNT162b1, BNT162b2, BNT162c1
Treatment period
Slightly decreased body weights and body weight gain were present in all test-item treated groups compared to controls. Body weight decreases were primarily due to decreases in body weight 24 h after dosing. However, body weight gain during the inter-dosing interval was similar to controls.

In summary, the absolute body weight was affected, but the body weight gain between dosing was not.

Recovery period
No noteworthy changes were noted.

Food and drinking water consumption

Treatment period
BNT162a1 - Group 2
The food consumption of the male and female animals treated with **30 µg BNT162a1/animal** appeared to be slightly decreased by up to 7.2% in test week 1 and 2. The effect is considered to be test item-related.

No test item-related influence was noted on the drinking water consumption by visual appraisal. The consumption was not quantified.

BNT162b1, BNT162b2, BNT162c1
No test item-related influence was observed on the food intake and the drinking water consumption.

Recovery period
No noteworthy changes were noted.

Body temperature

Treatment period
BNT162a1, BNT162b1, BNT162b2, BNT162c1
Intramuscular administration with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8 led to slightly increased body

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temperatures at 4 h p.a. and/or 24 h p.a. compared to the control animals. The effect appeared to be slightly more pronounced in the groups treated with the higher test item dose levels (i.e. groups 2, 5, 6, and 7).

Recovery period
During the recovery period, the body temperature remained at a slightly higher level compared to the control group in all previously test item treated groups.

Haematology and coagulation

Treatment period
The most consistent test item-related haematological changes were dose-related increases in neutrophils and large unstained cells (LUC), which were seen with all test items on test day 17, but were greatest in groups 2, 5 and 7 and were greater in females relative to males. Other test item-related changes included decreases in the absolute and relative reticulocyte count (test day 4 only), platelet count, and red cell mass (HGB, HCT and RBC; test day 17 only), and increases in the numbers of leucocytes, monocytes, eosinophils, basophils and/or fibrinogen concentrations.

BNT162a1 - Groups 2 and 3
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-5.

Recovery period
All changes fully reversed by the end of the recovery phase.

BNT162b1 - Groups 4 and 5
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, eosinophils, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-6.

Recovery period
All changes fully reversed by the end of the recovery phase.

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BNT162c1 - Group 6
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-7.

Recovery period
All changes fully reversed by the end of the recovery phase.

BNT162b2 - Group 7
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, eosinophils, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-8.

Recovery period
All changes fully reversed by the end of the recovery phase.

Clinical chemistry

Treatment period
BNT162a1, BNT162b1, BNT162b2, BNT162c1
An elevated plasma activity of gamma-glutamyltransferase (gamma-GT) was noted for all test item-treated groups in comparison to the control group as given in Text table 4-10. There were no macroscopic or microscopic findings consistent with cholestasis or hepatobiliary injury to explain the increased gamma-GT activity.

Further, a decrease in albumin plasma levels and an increase in globulin plasma levels, resulting in an altered albumin/globulin ratio, were observed in all test item treated groups. The changes are consistent with an acute phase response in albumin and globulin where albumin goes down and globulin goes up with inflammation, and the albumin/globulin ratio decreases.

Recovery period
The elevated plasma activity of gamma-GT had subsided in all previously test item-treated groups.

Urinalysis

Treatment and recovery period
No test item-related changes were noted.

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Immunogenicity assessment (performed by BioNTech SE, Germany)	The available data demonstrates that all BNT162 vaccine candidates elicited a SARSCoV-2 spike protein specific antibody response directed against the S1 domain and the RBD sub-domain. Antibody responses detected via ELISA directly translated into neutralizing activity as seen in the VSV/SARS-CoV2-S pseudovirus neutralization test with BNT162 vaccines showing higher antigen-specific antibody titers also displaying more pronounced virus neutralization effect. A comparison of the three RNA platforms with regard to their immunogenicity in rats may not be fully predictive for how they may perform relative to each other in human due to species-specific differences in immunity mechanisms.
Ophthalmological and auditory examination	No changes were noted.
Acute phase proteins	Treatment period **BNT162a1, BNT162b1, BNT162b2, BNT162c1** Elevated serum levels of the acute phase proteins alpha1-acid glycoprotein and alpha2 macroglobulin were noted for all test item-treated groups in comparison to the control group on test day 4 and test day 10 to 17 as given in Text table 4-14 and Text table 4-15. Recovery period The elevated serum levels of alpha1-acid glycoprotein and alpha2 macroglobulin noted during the treatment period had subsided in all previously test item-treated groups.
Cytokines	Treatment and recovery period **BNT162a1, BNT162b1, BNT162b2, BNT162c1** No test item-related changes were noted for any treatment. There were no general differences between the test item-treated groups and the control group and among the various test item-treated groups.
Macroscopic *post mortem* findings	Terminal sacrifice **BNT162a1, BNT162b1, BNT162b2, BNT162c1** Test item-related findings were noted for all test items and all dose levels in male and female animals as given in Text table 4-19, Text table 4-20 and Text table 4-21. All changes noted macroscopically were interpreted to be due to inflammation at the injection site and/or immune activation.

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Recovery sacrifice

All macroscopic findings noted in the spleen had subsided at the end of the 3-week recovery period.

Enlarged iliac lymph nodes were still noted for a few animals at the end of the 3-week recovery period as follows:

Group 4	
(30 μg BNT162b1/animal):	One of 5 females.
Group 5	
(100 μg BNT162b1/animal):	All 5 males, 2 of 5 females.
Group 7	
(100 μg BNT162b2/animal):	One of 5 males, 3 of 5 females.

Organ weights

Terminal sacrifice

BNT162a1, BNT162b1, BNT162b2, BNT162c1

The macroscopic findings of enlarged spleens correlated with increased relative and absolute spleen weights and are identified in Text table 4-22.

Recovery sacrifice

There were no noteworthy differences in the organ weights between the previously test item-treated animals and the control animals after 3-weeks of recovery.

Histopathology

Terminal sacrifice

Test item-related microscopic findings at the end of dosing were evident in injection sites and surrounding tissues, increased cellularity of germinal centres and increased plasma cells in the draining (iliac) lymph nodes, bone marrow, spleen, and liver.

For details on the findings at the injection sites refer to 'Local tolerance' further above.

Test item-related findings in the draining (iliac) lymph node were characterized by increased cellularity of the follicular germinal centres and increased plasma cells (plasmacytosis) which were variably present in all groups.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary haematopoiesis in the spleen (which correlated with increased spleen size and weight), and a test item-related vacuolation of hepatocytes in the portal regions of the liver were present in all groups. The liver findings were not associated with changes in markers of hepatocyte injury

(e.g. ALAT). While gamma-GT was elevated in test-item treated animals, it is not a marker of hepatocyte injury.

The test item-related findings are summarised in Text table 4-24, Text table 4-25 and Text table 4-26.

Recovery sacrifice

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland; skeletal muscle) and spleen were partially or completely recovered in all animals at the end of the recovery period. Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals, being less severe (minimal to mild) if not resolved; plasmacytosis in the iliac lymph node was less severe and present in fewer groups (**30** or **100 µg BNT162b1/animal** or **100 µg BNT162b2/animal**), indicating partial or complete recovery.

The test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary haematopoiesis in the spleen, and the vacuolation of hepatocytes in the portal regions of the liver were fully recovered.

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1.3 Conclusion

Intramuscular administration of 4 LNP-formulated RNA vaccines (based on 3 LNP-formulated RNA platforms) encoding viral proteins once weekly for 2 or 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity and produced the expected local inflammatory reaction. Treatment groups included: **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** on test days 1 and 8 (2 administrations).

No test item-related deaths were noted for any treatment. There were no test-item related ophthalmologic or auditory alterations. None of the animals of any treatment group revealed any test item-related systemic changes in behaviour, external appearance, or consistency of faeces.

Clinical findings included slightly decreased body weights and body weight gain and transient slight elevations in body temperatures at 4 and 24 h after dosing for all test-item treated groups compared to controls. Body weight decreases were primarily due to decreases in body weight 24 h after dosing; however, body weight gain during the inter-dosing interval was similar to controls. A slightly reduced food consumption was noted for the animals treated with **30 µg BNT162a1/animal** in test weeks 1 and 2.

Test-article related injection site observations included oedema, erythema, and induration; oedema was the most common finding, followed by erythema, and very rarely induration. The incidence was higher and observations were more severe after the second and or third dose administration compared to the first administration, but resolved prior to subsequent dosing and were fully recovered at the end of the 3-week recovery period. Macroscopic findings at the injection sites included induration or thickening, occasionally accompanied by incrustation, which was noted for nearly all test article-treated animals. This correlated microscopically to inflammation in all test article-administered animals. Inflammation was mixed to mononuclear with variable fibrosis, oedema, and myofiber degeneration (rare necrosis).

Inflammation was most severe in animals dosed with **100 µg BNT162b1/animal** or **100 µg BNT162b2/animal**, followed by **30 µg BNT162a1/animal**. The findings were typical of an inflammatory response to vaccine antigen and lipid nanoparticle. Inflammation was occasionally evident extending into tissues adjacent to the injection site. Inflammation at the injection site was accompanied by elevations in circulating white blood cells (granulocytes, monocytes, and LUC) and acute phase proteins (fibrinogen, alpha-2 macroglobulin, and alpha-1 acid glycoprotein).

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At the end of the 3-week recovery phase, all clinical injection site findings, clinical pathology findings and macroscopic observations had resolved and there was evidence of recovery of the injection site inflammation microscopically. The injection site findings were not interpreted as adverse because of limited severity, lack of systemic findings, and absence of clinical signs of lameness.

Test-article related macroscopic enlargement of the draining (iliac) lymph nodes was evident at the end of dosing. Microscopically, this finding correlated with increased cellularity of germinal centres and increased plasma cells in the draining (iliac) lymph node and is an anticipated immune response to the administered vaccine and LNP. At the end of the 3-week recovery, a few animals treated with **BNT162b1** or **BNT162b2** (30 μg and/or 100 μg/animal) still had slightly enlarged iliac lymph nodes. All other test item-related changes had subsided.

Effects considered secondary to immune activation/acute phase responses and inflammation at the injection site included transient reticulocyte decreases (test day 4 only), minimal decreases in RBC, HGB, and HCT on test day 17 only, and sporadic small magnitude decreases in platelets. Platelet reductions were likely due to inflammation-related platelet activation and consumption and were un-associated with other alterations in haemostasis. These effects had subsided after the 3-week recovery period.

Test-article related macroscopic enlargement of spleen and associated absolute and relative spleen weights correlated microscopically to increased haematopoiesis; this finding was resolved at the end of the 3-week recovery period. Increased haematopoiesis was also evident in the bone marrow. Both findings were secondary to inflammation at the injection site and were fully resolved at the end of the 3-week recovery period.

Test-article related microscopic vacuolation of portal hepatocytes was present in all groups, with a higher incidence in females than males for all but the groups that were administered **100 µg/animal BNT162b1** or **BNT162b2**. This finding was not adverse because it was unassociated with alterations in hepatic function (e.g. no elevations in ALAT) and was fully reversed at the end of the 3-week recovery period. This change may be related to hepatic clearance of the pegylated lipid in the LNP.

No test item-related changes were observed for cytokine serum levels.

Elevations in GGT were evident in all test-item treated animals. There were no macroscopic or microscopic findings consistent with cholestasis or hepatobiliary injury to explain the increased gamma-GT activity which was completely resolved at the end of the 3-week recovery period.

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Document 1

Immunogenicity assessment demonstrated that all BNT162 vaccine candidates elicited a SARSCoV-2 spike protein specific antibody response directed against the S1 domain and the RBD sub-domain. Antibody responses detected via ELISA directly translated into neutralizing activity as seen in the VSV/SARS-CoV2-S pseudovirus neutralization test with BNT162 vaccines showing higher antigen-specific antibody titers also displaying more pronounced virus neutralization effect.

In conclusion, administration of vaccine candidates **BNT162a1**, **BNT162b1**, **BNT162b2**, or **BNT162c1** via intramuscular injections weekly for 2 or 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity and produced nonadverse inflammatory changes at the injection sites and the draining lymph nodes, increased haematopoiesis in the bone marrow and spleen, and clinical pathology changes consistent with an immune response or inflammation in the injection sites. The findings in this study are reversible, consistent with those typically associated with the intramuscular administration of antigens and/or LNPs.

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17 Sep 2020
Date

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2. GENERAL INFORMATION

2.1 Aim of study

The aim of the study was to obtain information on the toxicity of four vaccines based on three LNP-formulated RNA vaccine platforms encoding for viral proteins administered once weekly by intramuscular administration to rats and to assess the reversibility of any effect after a 3-week recovery period.

2.2 Duration of study

- 5 to 11 adaptation days
- 17 test days for groups 1 to 5 and group 7
- 10 test days for group 6
- 3 additional weeks for the animals scheduled for the recovery period

2.3 Test items and control

2.3.1 Control (for group 1)

Designation	Buffer (PBS/300 mM Sucrose)
Batch no.	090320
Receipt no.	69570 (one vial with a gross weight of 66.76 g)
Date of receipt	13 March 2020
Characteristics	Liquid
Storage conditions	At +2°C to +8°C
Stability/Retest date	No data available to **LPT**. No Certificate of Analysis was available to **LPT**.
Retention sample	Stored in **LPT**'s archives.

2.3.2 Test item 1 (for groups 2 and 3)

Designation	"RBL063.3" (BNT162a1)
Content	LNP formulated uRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162a – 1")
Batch no.	CoVVAC/090320
Receipt no.	69571 (100 vials with 500 µL each)

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Date of receipt	13 March 2020
Characteristics	Frozen liquid (at receipt at **LPT**)
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	517 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in **LPT**'s archives.

2.3.3 Test item 3 (for groups 4 and 5)

Designation	"RBL020.3" (BNT162b1)
Designation	LNP formulated modRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162b - 1")
Batch no.	CoVVAC/100320
Receipt no.	69573 (100 vials with 500 µL each)
Date of receipt	13 March 2020
Characteristics	Frozen liquid (at receipt at **LPT**)
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	508 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in **LPT**'s archives.

2.3.4 Test item 4 (for group 7)

Designation	"RBP020.1" (BNT162b2)
Designation	LNP formulated modRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162b - 2")
Batch no.	CoVVAC/160320

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Receipt no.	69580 (100 vials with 500 µL)
Date of receipt	20 March 2020
Characteristics	Frozen liquid (at receipt at **LPT**)
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	554 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in **LPT**'s archives.

2.3.5 Test item 5 (for group 6)

Designation	"RBS004.3" (BNT162c1)
Designation	LNP formulated saRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162c - 1")
Batch no.	CoVVAC/130320
Receipt no.	69581 (70 vials with 500 µL)
Date of receipt	20 March 2020
Characteristics	Frozen liquid (at receipt at **LPT**)
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	430 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in **LPT**'s archives.

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2.3.6 Test item 2

Test item 2 was not scheduled to be used as test item in the study. However, 3 animals were treated erroneously with this test item (see also Section 3.7).

Designation	"RBL063.1" (BNT162a - 2)
Designation	LNP formulated modRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162a - 2")
Batch no.	CoVVAC/110320
Receipt no.	69572 (100 vials with 500 µL)
Date of receipt	13 March 2020
Characteristics	Frozen liquid (at receipt at **LPT**)
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	481 µg RNA/mL
Retention sample	Stored in **LPT**'s archives.

2.4 Identification of the test items

After receipt at **LPT**, the test items were inspected. Batch numbers, amounts, and characteristics (colour and consistency) were determined and compared with information given by the Sponsor (see text table below). Identification sheets were filed with the raw data.

Text table 2-1: Identification of the test item

Test item / Control	Parameter	LPT identification[#]	Sponsor identification[##]
Control: Buffer (PBS/300 mM Sucrose)	colour consistency	clear liquid	white to off-white suspension
BNT162a1	colour consistency	slightly turbid liquid	white to off-white suspension
BNT162b1	colour consistency	slightly turbid liquid	white to off-white suspension
BNT162b2	colour consistency	slightly turbid liquid	white to off-white suspension
BNT162c1	colour consistency	slightly turbid liquid	white to off-white suspension

[#] Identified before usage, in thawed condition, at room temperature.
[##] According to Certificates of Analysis, for the thawed conditions of the test items.

No further identification was performed by **LPT**.

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2.5 Sponsor / Test Facility / Responsible personnel

Sponsor	BioNTech RNA Pharmaceuticals An der Goldgrube 12 55131 Mainz Germany
Sponsor's contact person	s 22 [redacted]
Test Facility	**LPT** Laboratory of Pharmacology and Toxicology GmbH & Co. KG Redderweg 8 21147 Hamburg Germany Phone: +49 40 70 20 20 Fax: +49 40 70 20 22 60 E-mail: LPT@LPT-Hamburg.de
Branch facility	**LPT**, 24601 Löhndorf/Post Wankendorf Germany
Study Director	Until 31 May 2020 s 22 [redacted] As of 01 June 2020 s 22 [redacted]
Deputy Study Director	s 22 [redacted]
Test Facility Management	s 22 [redacted]
Haematology / Clinical chemistry / Coagulation / Cytokine Analysis / Blood sampling	s 22 [redacted]
Acute phase protein analysis	s 22 [redacted]
Veterinarian / Macropathology	s 22 [redacted] s 22 [redacted]
Histopathology	s 22 [redacted]
Statistics	s 22 [redacted]
Quality Assurance Unit (QAU)	s 22 [redacted]

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2.6 Rules and regulations

2.6.1 Good Laboratory Practice

The study was performed in compliance with the 'Good Laboratory Practice' regulations (see the Statement of Compliance on page 5 and the enclosed 'GLP Certificate of the Test Facility **LPT**' in Appendix 3).

2.6.2 Standard Operating Procedures and staff safety

Standard Operating Procedures (SOPs)	All work was carried out according to Standard Operating Procedures which were followed for all stages of the study. The SOPs could be inspected in those divisions, which were engaged in the study and in the Quality Assurance Unit (QAU).
Staff safety	The standard safety precautions operating within the department were applied to this study.

2.6.3 Archiving and storage

Archives of data and specimens

During the study

All data generated at the Branch Facility:

In the depot
LPT, 24601 Löhndorf/Post Wankendorf
Germany

All remaining data:

In the depot
LPT
Redderweg 8
21147 Hamburg
Germany

After reporting

The final report and the amendment no. 1 to final report will be archived by the Sponsor.

A copy of the final report, the amendment no. 1 to final report and all specimens, written raw data, and other study-related documents listed in the Study Plan section 'Study Materials to be Archived' are stored in the **LPT** archives. The duration of storage (15 years) will be in compliance with the GLP regulations as stated in the German Chemicals Act ("Chemikalien-gesetz").

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All archived study materials will be destroyed after the 15-year GLP storage period unless the Sponsor requests otherwise.

Upon expiry of the 15-year archiving period, the Sponsor will be given three weeks' notice before the study documentation and samples are destroyed by **LPT**. The Sponsor must respond within the 3-week notification period if testing documentation is to be transferred to the Sponsor (shipping fees will be billed). If **LPT** does not receive any response from the Sponsor, the study documentation and samples will be destroyed.

To avoid any doubt, it is the responsibility of the Sponsor to provide **LPT** with a valid contact. The archived documentation and samples will be destroyed without Sponsor notification after 15.5 years of archiving if **LPT** cannot contact the Sponsor because

- a valid Sponsor contact has not been provided
  or
- the Sponsor company no longer exists
  or
- **LPT** has not been advised of the legal successor.

Three months after the issuance of the Final Study Report, any samples or aliquots not listed in the Study Plan section 'Study Materials to be Archived' and still remaining at **LPT** will be listed. This list will be forwarded to the Sponsor who will decide which of these samples or aliquots will be dispatched and which samples or aliquots will be destroyed at **LPT**.

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2.7 Study dates

Code number of the study in the raw data: 38166

Start of study

Date of Study Plan: 16 March 2020

Study Plan amendments:
No. 1, dated 17 March 2020
No. 2, dated 23 March 2020
No. 3, dated 25 March 2020
No. 4, dated 03 April 2020
No. 5, dated 06 April 2020
No. 6, dated 08 April 2020
No. 7, dated 20 April 2020
No. 8, dated 29 May 2020
No. 9, dated 18 June 2020

Text table 2-2: In-life Schedule - Study dates

Animals	First administration	End of in-life period
All main study animals of groups 1, 2 and 4	17 March 2020	02 April 2020
All recovery animals of groups 1, 2 and 4	17 March 2020	23 April 2020
All main study animals of groups 3, 5 and 7	23 March 2020	08 April 2020
All recovery animals of groups 3, 5 and 7	23 March 2020	29 April 2020
All main study animals of group 6	23 March 2020	01 April 2020
All recovery animals of group 6	23 March 2020	22 April 2020
Three erroneously treated animals (non-GLP)	23 March 2020	26 March 2020
All satellite animals of groups 1, 2 and 4	24 March 2020	09 April 2020
All satellite animals of groups 3, 5 and 7	14 April 2020	30 April 2020
All satellite animals of group 6	14 April 2020	23 April 2020

Date of Final Report: 01 July 2020

Date of Amendment No. 1 to Final Report: 17 September 2020

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2.8 Study Plan deviations

The study was conducted in accordance with the Study Plan and 9 Study Plan amendments. There was no major deviation from the Study Plan and the Study Plan amendments. However, the following minor deviations were noted:

Animals

A few male and female animals exceeded the allowed body weight range of 10% of the mean weight for each sex at the time of selection. This deviation was due to the limited availability of animals that fully met the required body weight criteria from the breeder.

Two (2) of the 10 delivered female satellite animals designated for blood sampling via the femoral vein catheter showed inflammations at the vascular access button. Hence, these animals were excluded from the study. However, 9 of the 10 animals originally delivered were needed to start dosing as scheduled. Therefore, a female spare animal from the main study animals that was not equipped with a femoral vein catheter was inserted into the satellite group (no. 215). Blood sampling was performed by means of retrobulbar vein puncture from this animal.

Animal housing

A malfunctioning of the air conditioning system caused relative humidity values in the animal room that temporarily fell slightly below the lower admissible limit of 40% on a few test days. The room temperature did not exceed the maximum range during the study period.

Administration

On test day 15, the male animals nos. 32, 34, 37, 39 and 42, and the female animal no. 60 (all of group 2) were dosed intramuscularly in the left hind leg contrary to the previous administrations, which were performed in the right hind limb. This change was due to local tolerance findings (eschar formation) which developed after administration on test day 8. In the affected animals, both administration sites were fixed at necropsy and processed for histological examinations.

Organ weights

The spleen of the female animal no. 144 was not weighed during necropsy.

These minor deviations that were not covered by Study Plan amendments did not affect the validity and integrity of the scientific results obtained during the study.

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3. MATERIALS AND METHODS

3.1 Animals

Wistar Han rats supplied by Charles River Laboratories Germany GmbH were used in this study. The satellite animals were supplied with a pre-implanted femoral vein catheter for repeated blood sampling.

An initial health check was performed upon delivery of the animals. Only animals free of signs of illness were selected for the study.

The animals were allocated to the test groups based on body weight by means of a computerized randomization program (see Section 3.7). Animals with a body weight at the extremes of the weight distribution, if any, were excluded and replaced by healthy spare animals. No replacements occurred after the first dose had been administered.

Test species / Strain / Stock	Rat / Wistar / Crl:WI(Han) All satellite animals (except for no. 215, see Section 2.8) were equipped with a vascular access button to the femoral vein by the breeder.
Breeder	Charles River Laboratories, Research Models and Services, Germany GmbH Sandhofer Weg 7, 97633 Sulzfeld, Germany
Number and sex of animals	255 animals (129 males and 126 females) <u>Main study (MS)</u> 143 animals (70 + 3 males and 70 females) Due to the short-term change of test item and dose level - from 100 µg Test item 2 (BNT162a2)/animal to 10 µg BNT162a1/animal - for group 3 (according to Study Plan amendment no. 2), three male animals had already been dosed with the originally planned dose of 100 µg Test item 2 (BNT162a2)/animal. These three animals of group 3 were replaced by 3 spare animals (see also Section 3.7). <u>Recovery period (RP)</u> 70 animals (35 males and 35 females) In addition, 20 spare animals (10 males and 10 females) were available for possible replacement. Three of the male spare animals were used to replace the erroneously dosed animals (see above, and Text table 3-2). One of the female spare animals was used as a satellite animal (no. 215, see Section 2.8).

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	Satellite animals (SA) 42 animals (21 males and 21 females) In addition, 6 spare satellite animals (3 males and 3 females) were available for possible replacement. The satellite animals were supplied in two separate shipments (10 animals per sex for groups 1/2/4, and 14 animals per sex for groups 3/5/6/7) to **LPT**. Two (2) of the 10 animals of the shipment for groups 1/2/4 showed inflammations at the vascular access button and were excluded from the study. As 9 animals were needed to start dosing as scheduled, one female spare animal from the main study animals not equipped with a vascular access button was used as satellite animal (see further above).
Age (at 1st dosing)	Groups 1, 2, and 4: Males and females: 54 days Groups 3, 5, 6, and 7: Males and females: 60 days
Body weight (at 1st dosing)	Males: 252.8 to 343.9 g Females: 188.3 to 267.3 g
Selection of species	The rat is a commonly used rodent species for toxicity studies. It can receive the full human dose and develops an immune response similar to the expected human response after vaccination.
Identification of animals	After randomisation, each rat received a continuous number on the tail, either by tattoo or marker. Additionally, the animal cages were labelled with study number, animal ID number, sex, type of study, route of administration, and treatment group.
Adaptation period	Groups 1, 2, and 4: 5 days Groups 3, 5, 6, and 7: 11 days

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3.2 Housing and feeding

3.2.1 Diet

A certified commercial pellet diet (ssniff® R/M-H V1534, ssniff Spezialdiäten GmbH, 59494 Soest, Germany; see Appendix 2: 'Composition of the Diet') served as food. The food was offered *ad libitum*. Food residue was removed and weighed.

Periodic analysis of the food for contaminants based on EPA/USA[2] is conducted at least twice a year by LUFA-ITL[3] (see Appendix 2: 'Limitation for Contaminants in the Diet'). Certificates of analysis of the composition and for contaminants were provided by the manufacturer and were included in the raw data.

3.2.2 Drinking water

Drinking water was offered *ad libitum*.

Samples of drinking water are taken by Wasserwerk Wankendorf and periodic analyses are performed by LUFA-ITL according to the 'Deutsche Trinkwasser-verordnung 2001' [German Regulations on Drinking Water 2001][4] (see Appendix 2: 'Limitation for Contaminants in the Drinking Water').

In addition, drinking water samples taken at **LPT** are analysed by LUFA-ITL once a year for means of bacteriological investigations according to the 'Deutsche Trinkwasserverordnung 2001, Anlage 1' [German Regulations on Drinking Water 2001, Addendum 1].

3.2.3 Housing

The animals were kept singly in MAKROLON cages (type III plus) with a basal surface of approximately 39 cm × 23 cm and a height of approximately 18 cm at a room temperature of 22°C ± 3°C (maximum range) and a relative humidity of 55% ± 10% (maximum range). Deviations from the maximum range caused for example during cleaning procedures were dealt with in SOPs.

The rooms were lit (about 150 lux at approx. 1.5 meters room height) and darkened for periods of 12 hours each.

[2] EPA/USA, Proposed Health Effects Test Standards for Toxic Substances Control Act Test Rules, Federal Register 44, 27334 - 27375, May 1979.

[3] Landwirtschaftliche Untersuchungs- und Forschungsanstalt, Institut für Tiergesundheit und Lebensmittelqualität GmbH, 24107 Kiel, Germany.

[4] Version from 02 August 2013, revised on 20 December 2019.

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Granulated textured wood (Granulat A2, J. Brandenburg, 49424 Goldenstedt, Germany) was used as bedding material for the cages. The cages were changed and cleaned once a week.

Periodic analysis of the bedding material for contaminants based on EPA/USA is conducted at least once a year by LUFA-ITL (see Appendix 2: 'Limitation for Contaminants in the Bedding Material').

3.3 Dose selection

The dose levels for this study had been selected in agreement with the Sponsor based on the anticipated clinical doses.

3.4 Test item preparation

The test items were delivered ready-to-use.

The LNP suspensions for dosing were used within 6 hours after thawing.

Protocol:

1. The test item vials required were thawed by removing from the -80°C ±8°C storage and allowed to warm to room temperature (approximately 30 minutes).
2. Each vial was mixed by gently inverting three times. The vials were neither mixed vigorously nor vortexed.
3. The vial's flip cap was flipped off.
4. The needle was inserted through the stopper into a vial and the appropriate volume per animal withdrawn. The procedure was repeated until the total needed volume per animal had been obtained. A new syringe (including needle) was used for each animal.
5. After the last administration of a day, any remaining volumes of the thawed test items were discarded; remnants were not re-frozen or re-used.

3.5 Test item formulation analysis

As the test items were delivered ready-to-use no formulation analysis was required.

3.6 Administration

Route of administration	Intramuscular (i.m.) administration into the *Musculus biceps femoris* using a Microfine+ Syringe 0.5 mL, 0.33 mm (29G) × 12.7 mm (BD, 324824).

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Frequency of administration

Groups 1, 2, 3, 4, 5 and 7:
On test days 1, 8 and 15; in total 3 administration days at one-week intervals per animal.

Group 6:
On test days 1 and 8; in total 2 administration days at a one-week interval per animal.

Erroneously treated animals:
Single dose (2 administration sites) on test day 1

Administration volume

Groups 1 to 7:

Text table 3-1: Administration volume

Group	Number of administration sites	Administration volume per administration day [µL]	
		Per site	Per animal
1	2	100	200
2	1	60	60
3	1	20	20
4	1	60	60
5	2	100	200
6	1	70	70
7	2	100	200

Erroneously treated animals:
100 µL/administration site; 2 administration sites
In total 200 µL/animal/administration day

Dosages

Groups 1 to 7:
Group 1: Control (200 µL Buffer/animal)
Group 2: 30 µg BNT162a1/animal
Group 3: 10 µg BNT162a1/animal
Group 4: 30 µg BNT162b1/animal
Group 5: 100 µg BNT162b1/animal
Group 6: 30 µg BNT162c1/animal
Group 7: 100 µg BNT162b2/animal

Erroneously treated animals:
100 µg Test item 2 (BNT162a2)/animal

See the text table in Section 3.7 for details.

Selection of route of administration

According to clinical use. The intramuscular route is the anticipated route for human exposure to the test item.

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3.7 Group size and dose levels

The animals were allocated to 7 test groups by means of a computer generated randomisation program[5] and treated as given in the text table below.

Text table 3-2: Group distribution and dosing scheme

Group	Dose level [µg/animal] (Test item / Control)	Number and sex of animals MS + RP + SA	Animal no.		
			MS	RP	SA
1	0 (Buffer) Control	10 + 5 + 3 m 10 + 5 + 3 f	1 - 10 16 - 25	11 - 15 26 - 30	211 - 213 214 - 216
2	30 (BNT162a1)	10 + 5 + 3 m 10 + 5 + 3 f	31 - 40 46 - 55	41 - 45 56 - 60	217 - 219 220 - 222
3	10 (BNT162a1)	10 + 5 + 3 m 10 + 5 + 3 f	61 - 70 76 - 85	71 - 75 86 - 90	223 - 225 226 - 228
4	30 (BNT162b1)	10 + 5 + 3 m 10 + 5 + 3 f	91 - 100 106 - 115	101 - 105 116 - 120	229 - 231 232 - 234
5	100 (BNT162b1)	10 + 5 + 3 m 10 + 5 + 3 f	121 - 130 136 - 145	131 - 135 146 - 150	235 - 237 238 – 240
6	30 (BNT162c1)	10 + 5 + 3 m 10 + 5 + 3 f	151 - 160 166 - 175	161 - 165 176 - 180	241 - 243 244 - 246
7	100 (BNT162b2)	10 + 5 + 3 m 10 + 5 + 3 f	181 - 190 196 - 205	191 - 195 206 - 210	247 - 249 250 - 252
Erroneously treated animals[#1]	100 (Test item 2: BNT162a2)	0 + 0 + 3 m	—	—	253 - 255

m male
f female
MS Main study
RP Recovery period
SA Satellite animals for cytokine analysis (except animals nos. 253 to 255)

[#] The treatment of group 3 was changed from 100 µg Test item 2/animal, as stipulated in the original Study Plan (Test item 2 was designated "RBL063.1" (BNT162a - 2), see Section 2.3.6), to 10 µg BNT162a1/animal as per Amendment no. 2 to the Study Plan, dated 23 March 2020, the date of start of treatment for group 3 (see Section 2.7). As the treatment change for group 3 was communicated at very short notice, 3 male animals had already been dosed with 100 µg Test item 2 (BNT162a2)/animal as originally planned on test day 1. These three animals were replaced by 3 spare animals in group 3. The erroneously treated animals received the new animal numbers given above. Test item 2 (BNT162a2) was not further used in the study.

The satellite animals of groups 1 to 7 were used for blood sampling only (see Section 3.8.7.5). Following the last blood sampling, these animals were sacrificed but not dissected.

[5] Provantis® Integrated preclinical software, version 10.2, Instem LSS Ltd, Stone, Staffordshire ST15 0SD, United Kingdom.

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The erroneously administered animals (nos. 253 to 255) were observed for 48 h post dosing under Non-GLP conditions. Body weight (test day 1, and 24 and 48 h post injection), body temperature (24 and 48 h post injection) and local tolerance (24 and 48 h post injection) were recorded. Based on these observations, the Sponsor decided how to further proceed: These animals were neither subjected to laboratory examinations nor to blood sampling for cytokine analysis. The observations were only performed for scientific interest and were not part of the GLP study. The gathered observations are not included in this report, but were communicated separately to the Sponsor.

3.8 Observations

All in-life examinations described in the following subsections pertain only to the main study and recovery animals, i.e. the satellite animals were excluded from these examinations.

Dated and signed records of all activities related to the day-to-day running and maintenance of the study within the animal unit as well as to the group observations and examinations outlined in the Study Plan were recorded in appropriate documentation. In addition, observations related to individual animals were made throughout the study and recorded.

The following sections describe the observations made during the course of the study.

3.8.1 Clinical signs

The animals were observed individually before and after dosing at each time of dosing for any signs of behavioural changes, reaction to treatment or illness.

In addition, the animals were checked regularly throughout the working day from 7:00 a.m. to 3:45 p.m. (i.e. starting approximately at 7:00 a.m., 9:00 a.m., 11:00 a.m., 1:00 p.m. and 3:00 p.m.). On Saturdays and Sundays, the animals were checked regularly from 7:00 a.m. to 11:00 a.m. with a final check performed at approximately 3:30 p.m. (i.e. starting at approximately 7:00 a.m., 9:00 a.m., 11:00 a.m., and 3:00 p.m.).

Cageside observations included skin/fur, eyes, mucous membranes, respiratory and circulatory systems, somatomotor activity and behaviour patterns. The onset, intensity and duration of any signs observed were recorded.

Dated and signed records of appearance, change and disappearance of clinical signs of individual animals were maintained on clinical history sheets.

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Special attention was paid to the local tolerance at the injection sites (see Section 3.8.3 for details on the observation of erythema/eschar, oedema, induration/hardening).

3.8.2 Mortality

Further checks were made early in the morning and again in the afternoon of each working day to look for dead or moribund animals. On Saturdays and Sundays, a similar procedure was followed with a final check at approximately 3:30 p.m.

These provisions allowed for recording of premortal symptoms in detail and for performing post mortem examinations as soon as possible after exitus. However, no premature deaths occurred and no premature sacrifice was necessary.

3.8.3 Local tolerance

The local tolerance of the test item at the injection site was recorded for all main study and recovery animals at the following times:

- 4 h after each injection
- 24 h after each injection
- 48 h after each injection

  As irritations were still present at 48 h after injection, the observations of the respective animal was extended to every 48 h until the irritation had resolved (i.e. 96 h p.a. and 144 h p.a. if necessary).

The injection sites were assessed for

- erythema and eschar formation
- oedema formation
- induration/hardening following palpation

The reactions were scored with a grading similar to that based on DRAIZE (Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics, Association of Food and Drug Officials of the United States, Austin, Texas, 1959) as given in detail in the text tables following on the following page.

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Text table 3-3: Grading of erythema and eschar formation

Erythema and eschar formation	Value
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beef redness) or eschar formation (injuries in depth) preventing erythema reading	4

Text table 3-4: Grading of oedema formation

Oedema formation	Value
No oedema	0
Very slight oedema (barely perceptible)	1
Slight oedema (edges of area well defined by definite raising)	2
Moderate oedema (raised approx. 1 millimetre)	3
Severe oedema (raised more than 1 millimetre and extending beyond area of exposure)	4

Text table 3-5: Grading of induration/hardening

Grade of induration/hardening	Value
No induration/hardening	0
Very slight induration/hardening (barely perceptible)	1
Slight induration/hardening	2
Moderate induration/hardening	3
Severe induration/hardening	4

If there were two injection sites per animal (left/right side), individual values for each of the two injection sites were only recorded in case the gradings of the sites were different (e.g. '0/1'). If the gradings of the two injection sites were identical only one scoring was recorded.

In addition, any signs of pain were recorded as general observations of local tolerance.

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3.8.4 Body weight

The body weight of each rat was recorded at the following times:

- at group allocation
- prior to each administration: on test days 1, 8, and 15 (if applicable)
- one day after each administration: on test days 2, 9, and 16 (if applicable)
- twice weekly during the recovery period
- at autopsy (i.e. during the process of necropsy, i.e. after fasting overnight and exsanguination, see Section 3.8.10.1 for details)

3.8.5 Food and drinking consumption

The quantity of food left by individual animals was removed, weighed, and recorded on a weekly basis throughout the experimental period. The residue was discarded.

The food intake per animal (g/animal/week) was calculated using the total amount of food given to and left by each rat in each group on completion of a treatment week. Weekly mean values were calculated for individual animals.

The relative food consumption (in g/kg b.w./day) was calculated as follows:

$$\text{Relative food consumption (g/kg b.w./day)} = \frac{\text{Total food given (g) - Total food left (g)}}{\text{Number of animal days}^{\#} \times \text{Body weight (kg)}}$$

[#] The term 'animal days' counts one animal day for each animal alive for a whole day; it is assumed that on the day of death an animal does not eat.

The drinking water consumption was monitored daily by visual appraisal throughout the study. The consumption was not quantified.

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3.8.6 Body temperature

The body temperature was determined using an anal probe at the times stated in the text table below.

Text table 3-6: Time points for body temperature measurement

Test day	Time points for body temperature measurement relative to dosing	Groups or animal number	Main study animals	Recovery animals
1	4 hours after 1st injection	1 to 7	X	X
2	24 hours after 1st injection	1 to 7	X	X
3	48 hours after 3rd injection[#]	No. 171		
8	4 hours after 2nd injection	1 to 7	X	X
9	24 hours after 2nd injection	1 to 7	X	X
15	1 week after last administration	6 and 7		X
15	4 hours after 3rd injection	1 to 5	X	X
16	24 hours after 3rd injection	1 to 5	X	X
17	48 hours after 3rd injection[##]	No. 149		
22	1 week after last administration	1 to 5		X
22	2 weeks after last administration	6 and 7		X
29	2 weeks after last administration	1 to 5		X
29	3 weeks after last administration	6 and 7		X
36	3 weeks after last administration	1 to 5		X

[#] The female animal no. 171 (group 6) revealed a body temperature of 40.0°C on test day 2 (i.e. 24 h after 1st injection on test day 1). For this animal, an additional body temperature measurement was conducted on test day 3 at 48 h after injection.

[##] The female animal no. 149 (group 5) revealed a body temperature of 40.2°C on test day 16 (i.e. 24 h after 3rd injection on test day 15). For this animal, an additional body temperature measurement was conducted on test day 17 at 48 h after injection.

3.8.7 Laboratory examinations

Blood samples were taken from the retrobulbar venous plexus under isoflurane anaesthesia from animals fasted overnight. The blood samples were collected into tubes as follows:

EDTA anticoagulant (whole blood).....for haematological investigations
Citrate anticoagulant (plasma)..... for coagulation tests
Li-Heparin anticoagulant (plasma) .....for clinical chemistry tests
Serum (no anticoagulant) .....for acute phase proteins and dose exposure

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The male animal no. 130 died during the blood withdrawal on test day 17. The blood sample intended for clinical chemistry tests was obtained by heart puncture from this animal. As a result, the plasma levels of phosphate and potassium, and the enzyme activities of ASA and LDH were far beyond the normal range for these parameters. Therefore, these data were excluded from statistical analysis (marked by 'E!' in Table 1-2).

3.8.7.1 Haematology

The blood samples were obtained as follows:

- On test day 4:	The first 5 surviving main study animals per sex and group and all recovery animals (n = 10 per group).
- At main study termination (on the day of dissection):	All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection):	All recovery animals (n = 5 per group).

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The haematological parameters listed in the text table below were determined.

Text table 3-7: Haematological parameters

Parameter	Unit	Instrument
Haemoglobin content (HGB)	mmol/L	ADVIA™ 120 Siemens Diagnostics GmbH 35463 Fernwald Germany
Erythrocytes (RBC)	$10^6/\mu L$	
Leucocytes (WBC)	$10^3/\mu L$	
Reticulocytes (Reti), relative	%	
Reticulocytes (Reti), absolute	$10^3/\mu L$	
Platelets (PLT)	$10^3/\mu L$	
Haematocrit value (HCT)	%	
Differential blood count (relative)#	%	
Differential blood count (absolute)#	$10^3/\mu L$	
Mean corpuscular volume (MCV)	fL	
Mean corpuscular haemoglobin (MCH)	fmol	
Mean corpuscular haemoglobin concentration (MCHC)	mmol/L	
Mean platelet (thrombocyte) volume (MPV)	fL	
Relative volume of thrombocytes / Plateletcrit (PCT)	%	
Platelet distribution width (PDW)	%	
Red cell distribution width (RDW)	%	
Mean platelet component (MPC)	g/dL	

Neutrophilic, eosinophilic and basophilic granulocytes, lymphocytes, and monocytes. Large unstained cells were simultaneously quantified during measurement of the differential blood count.

Following the haematological examinations using the ADVIA system, blood smears were prepared from all samples, dried, and stained as given in the text table on the following page.

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Text table 3-8: Staining of blood smears

Dissection	Group	Number of stainings	
		Pappenheim	Brilliant Cresyl blue
Test day 4	Groups 1, 2 and 4	1	0
	Groups 3, 5, 6 and 7	1	0
Main study	Groups 1, 2 and 4	1	1
	Group 6	1	1
	Groups 3, 5 and 7	1	1
Recovery	Groups 1, 2 and 4	1	1
	Group 6	1	1
	Groups 3, 5 and 7	1	1

The stained blood smears may be evaluated, if requested by the Sponsor (details are to be stated in a Study Plan amendment). So far, no evaluation of blood smears was performed by **LPT**.

3.8.7.2 Coagulation

The blood samples were obtained as follows:

- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group)

The coagulation parameters listed in the text table below were determined.

Text table 3-9: Coagulation parameters

Parameter	Unit	Instrument
Prothrombin time (PT)	sec	Amax Destiny Plus™ Tcoag Deutschland GmbH 32657 Lemgo, Germany
Activated partial thromboplastin time (aPTT)	sec	
Fibrinogen	mg/dL	

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3.8.7.3 Clinical chemistry

The blood samples were obtained as follows:

- On test day 4: The first 5 surviving main study animals per sex and group and all recovery animals (n = 10 per group).
- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group).

The clinical chemistry parameters listed in the text table below were determined.

Text table 3-10: Clinical chemistry parameters

Parameter	Unit	Instrument / Method
Albumin	g/L plasma	KONELAB 30i (see below)
Globulin	g/L plasma	By subtraction
Albumin/globulin ratio	(non-dimensional)	By calculation
Bilirubin (total)	µmol/L plasma	KONELAB 30i Thermo Fisher Scientific 63303 Dreieich Germany
Cholesterol (total)	mmol/L plasma	
Creatinine	µmol/L plasma	
Glucose	mmol/L plasma	
Phosphate	mmol/L plasma	
Protein (total)	g/L plasma	
Urea (in blood)	mmol/L plasma	
Triglycerides	mmol/L plasma	
Calcium	mmol/L plasma	
Chloride	mmol/L plasma	
Potassium	mmol/L plasma	
Sodium	mmol/L plasma	
Alanine aminotransferase (ALAT)	U/L plasma	
Alkaline phosphatase (aP)	U/L plasma	
Aspartate aminotransferase (ASAT)	U/L plasma	
Lactate dehydrogenase (LDH)	U/L plasma	
Creatine kinase (CK)	U/L plasma	
Gamma-glutamyltransferase (Gamma-GT)	U/L plasma	

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3.8.7.4 Analysis of acute phase proteins

Blood samples were obtained as follows:

- On test day 4: The first 5 surviving main study animals per sex and group and all recovery animals (n = 10 per group).
- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group).

In order to obtain approximately 4 × 75 µL serum per animal and sampling time, approx. 0.7 mL whole blood per animal and sampling time were collected in serum separator tubes (Sarstedt AG & Co., Germany). The blood samples were allowed to clot at room temperature for at least 30 minutes, and centrifuged afterwards in order to obtain serum. Immediately after centrifugation, the serum was divided into aliquots and frozen at -20°C ±2°C until analysis at **LPT** using commercial ELISA test kits purchased from Abcam PLC, Cambridge, United Kingdom (see text table below) and a Tecan Sunrise microplate reader (Tecan Deutschland GmbH, 74564 Crailsheim, Germany).

Text table 3-11: Parameters of acute phase protein analysis

Acute phase protein	Matrix	Sample volume	Number of aliquots (aliquot volume)	Storage temperature	Method
Alpha1-acid glycoprotein	Serum	150 µL	2 (75 µL)	-20°C ±2°C	Rat Alpha 1 Acid Glycoprotein / AGP ELISA Kit (ab157729, lot no. GR3235007-3)
Alpha2 macroglobulin	Serum	150 µL	2 (75 µL)	-20°C ±2°C	Rat alpha 2 Macroglobulin ELISA Kit (ab157730, lot nos. GR3322797-1, GR3322797-3, and GR3322797-4)

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3.8.7.5 Cytokine analysis

Blood samples for cytokine analysis were taken from the femoral vein catheter of all satellite animals at the times given in the text table below.

Text table 3-12: Blood sampling schedule for cytokine analysis

Test day	Sampling time relative to dosing	Animal numbers of satellite animals used							Number of samples/ aliquots
		Group 1[#]	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	
1	Prior to 1st dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
1	6 h post 1st dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
8	Prior to 2nd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
8	6 h post 2nd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
10	48 h post 2rd dosing						241 to 246		6/12
15	Prior to 3rd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240		247 to 252	36/72
15	6 h post 3rd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240		247 to 252	36/72
17	48 h post 3rd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240		247 to 252	36/72
								Total number of samples / aliquots:	**282/564**

[#] Blood sampling from the female animal no. 215 was performed by means of retrobulbar vein puncture (refer to Section 2.8 and Section 3.1).

Sufficient whole blood was collected from the animals in order to obtain at least 2×75 µL serum per animal and sampling time. The serum samples were frozen, stored and analysed as given in Text table 3-15 below.

Text table 3-13: Parameters of cytokine analysis

Cytokine	Matrix	LLOQ [pg/mL]	Sample volume	Number of aliquots (aliquot volume)	Storage temperature	Method
IFN-γ TNF-α IL-1-β IL-6 IL-10	Serum	4.0 7.1 12.6 3.0 9.9	150 µL	2 (75 µL)	-20°C ± 2°C	Cytometric bead array (ProcartaPlex) using a Cytomics FC 500 flow cytometer (Beckman Coulter GmbH, 47704 Krefeld, Germany)

LLOQ lower limit of quantification

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3.8.7.6 Urinalysis

Urine samples were collected from animals at the following time points:

- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group).

The urine was collected in a URIMAX funnel cage for 16 hours. The collection of urine was terminated immediately prior to the blood withdrawals for haematological and clinical chemistry examinations. The parameters measured and the methods used are given in the text table below.

Text table 3-14: Urinary parameters

Parameter	Unit	Instrument
Volume	mL	Graduated vessel
pH	n/a	Digital pH meter (type WTW InoLab pH 720)
Specific gravity	g/mL	Kern Refractometer (type ORA 2PA), sample compared with water (nominal value of 1.000)

In addition, the tests given in the text table below were performed using qualitative indicators (Combur 9® Test, Roche Diagnostics GmbH, 68305 Mannheim, Germany) of analyte concentration:

Text table 3-15: Analytes of qualitative urinalysis

Parameter	Reporting convention					
	Unit	Semi-quantitative determination level				
Protein	g/L	neg	0.3	1	5	
Glucose	mmol/L	normal	2.8	5.5	17	55
Bilirubin	-	neg	+	+ +	+ + +	
Urobilinogen	µmol/L	normal	17	70	140	200
Ketones	-	neg	+	+ +	+ + +	
Haemoglobin (Hb, approx. values)	ery/µL	neg	10	25	50	250
Nitrite	-	neg	pos			

neg = negative
pos = positive
ery = erythrocyte count

\+ 'Small amount' of analyte
+ + 'Moderate amount' of analyte
+ + + 'Large amount' of analyte

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A microscopic examination of urine samples was carried out by centrifuging samples and spreading the resulting deposit on a microscope slide. The deposit was examined for the presence of the following parameters:

- Epithelial cells
- Leucocytes
- Erythrocytes
- Organisms
- Further constituents (i.e. sperm, casts)
- Crystalluria

The frequency of the above parameters in the centrifugal deposit was recorded as follows:

0	None found in any field examined
+	Few in some fields examined
+ +	Few in all fields examined
+ + +	Many in all fields examined

The colour and the turbidity of the urine were examined visually.

3.8.8 Blood sampling for dose exposure

In order to obtain serum samples for dose exposure examination (10 aliquots of approximately 100 µL each per animal), blood was withdrawn from the retrobulbar venous plexus under isoflurane anaesthesia from animals fasted overnight as follows:

- At main study termination (on the day of dissection): All main study animals.
- At the end of the recovery period (on the day of dissection): All recovery animals

In total 209 samples (2074 aliquots) were collected. No blood sample for dose exposure examination could be collected from the male animal no. 130 (group 6) as the animal died during blood withdrawal on test day 17 such that only the samples for the laboratory examinations could be obtained. Further, for a few animals, the blood volume sampled was not sufficient for 10 aliquots of 100 µL serum each but yielded only 7 to 9 aliquots.

After collection of sufficient whole blood in serum separator tubes (Sarstedt®, Germany), the blood samples were allowed to clot for at least 30 minutes before centrifugation. Immediately after centrifugation, the serum was frozen and stored at -80°C ±8°C until shipment for analysis.

The samples were labelled with the study number, species, animal number, type of sample, purpose (dose exposure), aliquot no., group number, test day and date.

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Following advance notice by e-mail (to: [redacted] and [redacted]), the dose exposure samples were dispatched on dry ice via courier as given in the text table below.

Text table 3-16: Shipping schedule of dose exposure samples

Shipped by LPT	Delivered to the Sponsor	Animals	Aliquots included	Consignee
06 Apr 2020	07 Apr 2020	Groups 1, 2, 4, 6 Main Study N = 80	Aliquots 1 to 10[#] (n = 790)	BioNTech RNA Pharmaceuticals [redacted]/ An der Goldgrube 12 55131 Mainz Germany
09 Apr 2020	09 Apr 2020	Groups 3, 5[##], 7 Main study N = 60	Aliquots 1 to 10[#] (n = 586)	
30 Apr 2020	30 Apr 2020	Groups 1 to 7 Recovery N = 70	Aliquots 1 to 10[#] (n = 698)	

[#] As far as available. For a few animals, less than 10 aliquots (but at least 7 aliquots) per sampling were available as the blood volume sampled was not sufficient to yield 10 aliquots of 100 µL serum each.

[##] No blood sample could be collected from the male animal no. 130 (group 6) as the animal died during blood withdrawal.

The samples were analysed for immunogenicity of the test items by BioNTech SE, Germany, under the responsibility of the Sponsor. An analytical report was forwarded to **LPT** (see Section 4.12 and Appendix 4).

3.8.9 Ophthalmological and auditory examinations

Examinations were performed on all main study and recovery animals before first dosing and at the end of the dosing period (groups 1 to 5 and 7: test day 16, group 6: test day 9), and for all recovery animals at the end of the recovery period (groups 1 to 5 and 7: test day 37, group 6: test day 30).

The eyes were examined with a HEINE ophthalmoscope. After examination of the pupillary reflex, mydriasis was produced by instillation of STULLN® eye drops (Ankerpharm GmbH, 07407 Rudolstadt, Germany) onto the cornea.

The following ocular structures were examined:

- Adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva
- Cornea, anterior chamber
- Lens, vitreous body, fundus (retina, optic disc)

The auditory acuity was checked with a simple noise test.

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3.8.10 Pathology and histopathology

3.8.10.1 Necropsy

For groups 1 to 5, and 7, necropsy was scheduled for test day 17 (approximately 48 hours after the last administration) for the main study animals and for test day 38 for all animals allocated to the recovery period.

For group 6 necropsy was scheduled for test day 10 (approximately 48 hours after the last administration) for the main study animals and for test day 31 for all animals allocated to the recovery period.

The animals were sacrificed and dissected following a randomization scheme.

The animals were euthanized by carbon dioxide (CO_2) inhalation, exsanguinated by cutting the aorta abdominalis, weighed, dissected, and inspected macroscopically under the direction of a pathologist.

All superficial tissues were examined visually and by palpation. The cranial roof was removed to allow observation of the brain, pituitary gland and cranial nerves. After ventral midline incision and skin reflection, all subcutaneous tissues were examined. The condition of the thoracic viscera was noted with due attention to the thymus, lymph nodes and the heart.

The abdominal viscera were examined before and after removal; the urinary bladder was examined externally and by palpation. The gastro-intestinal tract was examined as a whole, and stomach and caecum were incised and examined. The lungs were removed and all pleural surfaces were examined under suitable illumination. The liver and the kidneys were examined. Any abnormalities in the appearance and size of the gonads, adrenal glands, uterus, intraabdominal lymph nodes and accessory reproductive organs were recorded.

None of the satellite animals was dissected and examined macroscopically as none of these animals had deceased or was prematurely sacrificed.

The erroneously administered animals (see Section 3.7) were not dissected.

The animals no. 76 and no. 130 which died during blood withdrawal closely before the pending terminal sacrifice on test day 17 were dissected immediately after the incident.

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The organs listed in the text table below were weighed before fixation.

Text table 3-17: Weighed organs

Weighed organs	
Adrenal gland (2)	Ovary (2)
Brain	Pituitary gland
Epididymis (2)	Prostate
Heart	Spleen
Kidney (2)	Testicle (2)
Liver	Thymus
Lungs	Thyroid (1, including parathyroids)
Lymph nodes (one cervical, one mesenteric)	

The paired organs were identified as left or right and weighed individually.

Organ/body weight ratios were calculated (using the body weight at autopsy obtained after exsanguination at necropsy) and are presented as relative organ weights (in g/kg b.w.).

3.8.10.2 Organ preservation

The organs or parts of organs of all animals listed in the text table on the following page were fixed in 7% neutral buffered formalin, except for the eyes which were fixed in Davidson's solution, and the testes which were fixed in modified Davidson's solution for optimum fixation.

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Text table 3-18: Tissues collected for preservation

Tissues preserved for histopathology	
Adrenal gland *(2)*	Mammary gland
# Animal ID	Muscle *(skeletal, leg)*
Aorta abdominalis	Nerve *(sciatic)*
# Body cavity, nasal	# Nerve *(tibial, 2)*
Bone *(os femoris with joint)*	Oesophagus
Bone *(sternum)*	Ovary *(2)*
Bone marrow *(os femoris)*	Oviducts *(2)*
Brain *(cerebrum, cerebellum, brain stem)*	Pancreas
Caecum	Parathyroids
# Clitoral gland *(2)*	Pituitary
Epididymis *(2)*	# Preputial gland *(2)*
Eye with optic nerve *(2)*	Prostate
# Ganglion, dorsal root, lumbar	Salivary glands *(mandibular, parotid, sublingual)*
Gut-associated lymphoid tissue	
Harderian gland *(2)*	Seminal vesicle *(2)*
Heart *(left and right ventricle, septum)*	Skin *(left flank)*
Injection sites 1 and 2	Spinal cord *(3 sections)*
Intestine, small *(duodenum, jejunum, ileum, Swiss roll method)*	Spleen
	Stomach
Intestine, large *(colon, rectum)*	Testicle *(2)*
Kidney and ureter *(2)*	Thymus
Lacrimal gland *(extraorbital)*	Thyroid *(2)*
# Larynx	Tongue *(including base)*
Liver *(2 lobes)*	Trachea
Lungs *(with mainstem bronchi and bronchioles)*	# Ureter *(2)*
Lymph node *(1, cervical)*	Urinary bladder
Lymph node *(1, mesenteric)*	Uterus *(including cervix)*
# Lymph node *(2, mandibular)*	Vagina
Lymph node *(1, draining administration site: iliac)*	# Zymbal's gland *(2)*

The tissues marked with the hash sign ('#') were preserved, but not further processed. They may be evaluated if requested by the Sponsor. So far, no evaluation was performed by **LPT**.

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3.8.10.3 Bone marrow

During dissection, fresh bone marrow was obtained from the os femoris (3 air-dried smears per animal) of the first 5 main study animals per sex and group, and of all recovery animals and stained as given in the text table below.

Text table 3-19: Staining of bone marrow smears

Dissection	Group	Number of stainings	
		Pappenheim	Giemsa
Main study (5 animals per sex and group)	Groups 1, 2 and 4	1	0
	Group 6	1	0
	Groups 3, 5 and 7	1	2
Recovery (5 animals per sex and group)	Groups 1, 2 and 4	1	2
	Group 6	1	2
	Groups 3, 5 and 7	1	2

The stained bone marrow smears may be evaluated, if requested by the Sponsor (details are to be stated in a Study Plan amendment). So far, no evaluation of bone marrow smears was performed by **LPT**.

3.8.10.4 Histopathology

The organs listed in Section 3.8.10.2, with the exception of the organs marked with the hash sign ('#'), of all main study and recovery animals of all groups were examined histopathologically after preparation of paraffin sections and haematoxylin-eosin staining.

Parathyroids cannot always be identified macroscopically. They were examined microscopically if in the plane of section and in cases they were noted as grossly enlarged.

Blood smears prepared for haematological examination (see Section 3.8.7.1) are available for a possible examination of pathological changes but may be examined and evaluated only depending on necropsy findings and upon agreement with the Sponsor. So far, no examination was performed.

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3.8.11 Statistics

All toxicology and pathology data were captured, as far as possible, using the departmental computerized systems (Provantis® Integrated preclinical software, version 10.2, Instem LSS Ltd., Stone, Staffordshire ST15 0SD, United Kingdom). Raw data not fully compatible with the computerized systems were maintained on paper according to appropriate SOPs.

The test item-treated groups 2 to 5 and 7 were compared to the control group 1. The test item-treated group 6 was compared to the control group 1 as far as possible. Due to the earlier sacrifice of the animals of group 6 (main study animals: test day 10, recovery animals: test day 31), the following parameters of group 6 were statistically compared to the control group on test day 4 only:

- Haematology and coagulation
- Clinical chemistry
- Urinalysis
- Cytokines
- Acute phase proteins
- Relative and absolute organ weights

The statistical methods described in the text table below were used for the data captured with the Provantis system.

Text table 3-20: Statistical methods

Statistical method	Parameters analysed
Multiple t-test based on DUNNETT, C. W. New tables for multiple Comparisons with a control *Biometrics,* 482-491 (Sept 1964)	Body weight / Food consumption / Haematology and coagulation / Clinical chemistry / Acute phase proteins / Urinalysis / Cytokines / Relative and absolute organ weights ($p \leq 0.05$ and $p \leq 0.01$)
Exact test of R. A. FISHER (if applicable)	Histopathology ($p \leq 0.05$)

The following settings were used for the statistical evaluation of the parametrical values captured by Provantis (see flow chart of decision tree on page 59):

Homogeneity of variances and normality of distribution were tested using BARTLETT's test and SHAPIRO-WILK's test. In case of heterogeneity and/or non-normality of distribution, stepwise transformation of the values into logarithmic or rank values was performed prior to ANOVA. If the ANOVA yielded a significant effect ($p \leq 0.05$), intergroup comparisons with the control group were made by DUNNETT's test (see above).

The statistical procedures were used for all data. Statistically significantly different data are indicated in the tables of Section 5 ('TABLES') of the report.

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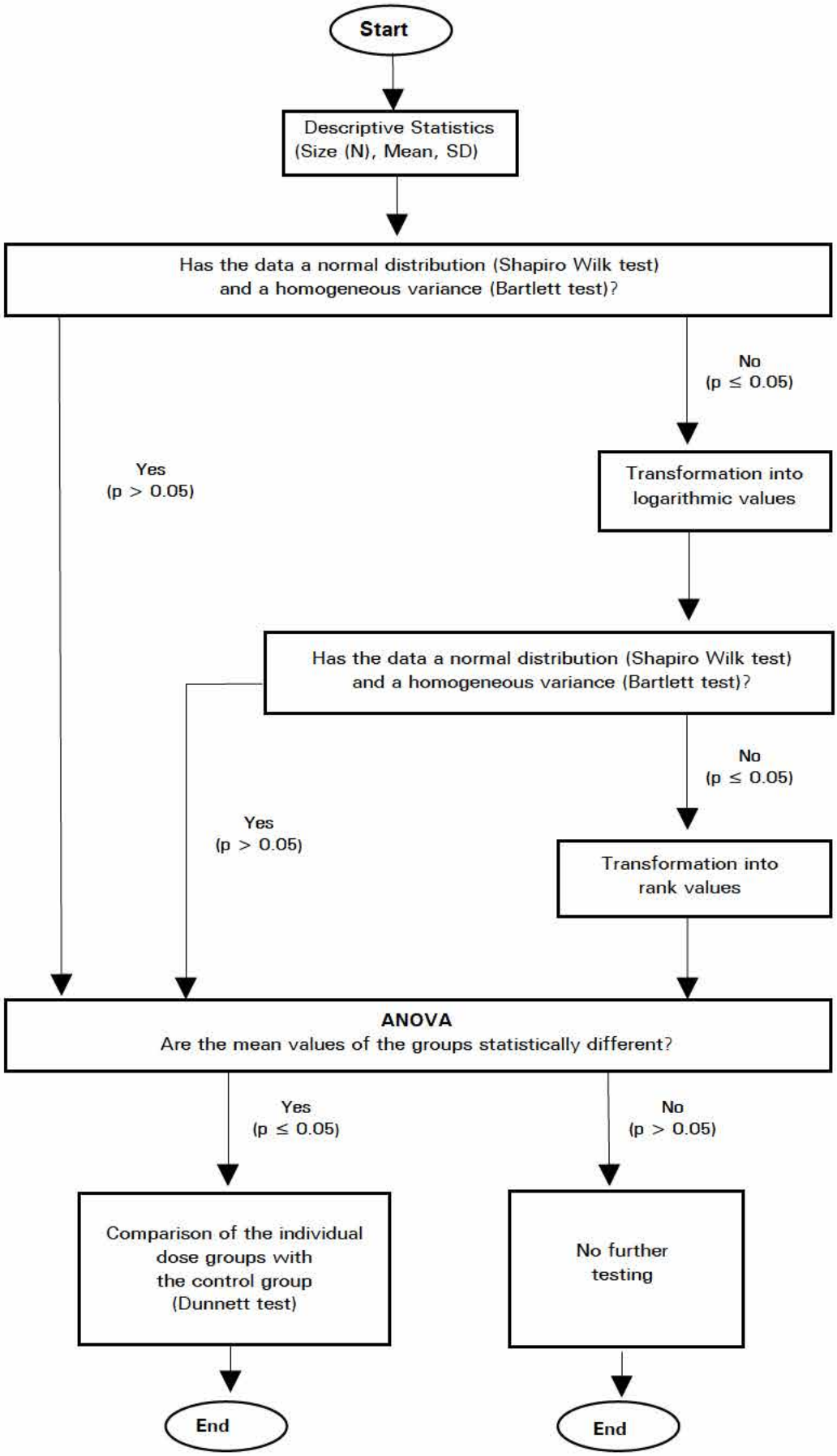
Flow Chart of Decision Tree of ANOVA and Dunnett's Test Calculation



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4. RESULTS

4.1 Local tolerance

BNT162a1 - Groups 2 and 3

Treatment period

Very slight to moderate oedema were noted for all animals following the 1st, 2nd, and/or 3rd injection of **10** or **30 µg BNT162a1/animal** on test days 1, 8, and 15.

Male and female animals treated with **10** or **30 µg BNT162a1/animal** (group 2) revealed very slight to well-defined erythema following the 1st or 2nd injection (up to 96 h after administration), and/or the 3rd injection (up to 48 h after administration). In addition, all male and female animals of administered **30 µg BNT162a1/animal** revealed a scabby skin at the injection site at 96 h after the 1st administration (on test day 4, see column 'F' in Table 1-2). Severe erythema (grade 4) for 5 of 15 male animals and 4 of 15 female animals treated with **10 µg BNT162a1/animal** (group 3) was noted on test day 14 (144 h after the 2nd administration on test day 8), but was resolved prior to the 3rd injection.

Further, the injection site appeared to be painful for 4 of 15 male animals and 12 of 15 female animals treated with the high dose of **30 µg BNT162a1/animal** on test day 9 (for one male animal also on test day 10) following administration of the 2nd dose on test day 8.

On test day 14 (day before 3rd administration), eschar formation was observed at the injection site for 5 male and 6 female animals treated with of **30 µg BNT162a1/animal** (group 2). Therefore, on test day 15, the male animals nos. 32, 34, 37, 39 and 42, and the female animal no. 60 were dosed intramuscularly in the left hind leg instead of the right hind leg as during the previous administrations. In the affected animals, both administration sites were fixed at necropsy and processed for histological examinations.

The macroscopic inspection at necropsy revealed an indurated and/or thickened injection site for all main study animals treated with **30 µg BNT162a1/animal** and for the majority of animals treated with **10 µg BNT162a1/animal**. For a few animals, an incrustation was noted at the injection site (high dose: 2 males and 2 females, low dose: one male).

All findings described above are considered to be test item-related based on the increases incidence and/or severity observed compared with buffer controls. The findings are considered to be related to immune responses at the site of vaccine administration.

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Recovery period

Very slight to slight oedema were still noted for nearly all animals previously treated with **10** or **30 µg BNT162a1/animal** during the early part of the recovery period (following the 3rd injection on test day 15). No dose-dependency was observed. All oedema had subsided as of test day 29 (i.e. 336 h after the last administration) at the latest.

All male and female animals administered **30 µg BNT162a1/animal** revealed severe erythema (grade 4) at 96 h after the last test item injection (test day 19). In the majority of animals, this skin reddening had subsided at 240 h p.a. (test day 25). Only 2 male and 2 female animals revealed erythema up to 432 h p.a. (test day 33). The skin reddening is considered to be test item-related.

At the end of the recovery, any local skin reactions with regard to erythema, oedema, indurations, and/or hardenings had subsided.

No abnormalities were noted at the injection site(s) of any animal at macroscopic inspection at necropsy at the end of the recovery period.

BNT162b1 - Groups 4 and 5

Treatment period

Very slight (mostly) to moderate (rarely) oedema were noted for all animals following the 1st, 2nd, and/or 3rd injection of **30** or **100 µg BNT162b1/animal** on test days 1, 8, and/or 15. In the high dose group 5, the two injection sites were occasionally affected to a different degree. In addition, individual animals of the low dose group treated with **30 µg BNT162b1/animal** (group 4) also revealed very slight erythema, observed only at 24 h following injection. No dose-dependency was observed for the skin reactions. All effects had subsided by 96 h p.a. after each of the first two injections.

Severe erythema (grade 4) for 3 female animals (nos. 136, 137, and 146) treated with **100 µg BNT162b1/animal** (group 5) was observed only on test day 14 (144 h after the 2nd administration on test day 8) and is considered test item related. This observation was no longer present prior to the 3rd injection.

An indurated and/or thickened injection site was noted for 7 male and 6 female animals per group and dose level for the main study animals treated with **30** or **100 µg BNT162b1/animal** at macroscopic inspection at necropsy.

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Recovery period

Very slight (mostly) to well-defined (rarely) oedema for nearly all animals administered **30 µg BNT162b1/animal**, and very slight (mostly) to moderate (rarely) oedema for nearly all animals administered **100 µg BNT162b1/animal** were still noted during the early part of the recovery period (following the 3rd injection on test day 15). All oedema had subsided by test day 35 (i.e. 480 h after the last administration).

No abnormalities were noted at the injection site(s) of any animal at macroscopic inspection at necropsy at the end of the recovery period.

BNT162c1 - Group 6

Treatment period

Very slight (mostly) to moderate (rarely) oedema were noted for all animals following the 1st and/or 2nd injection of **30 µg BNT162c1/animal** on test days 1 and/or 8. In addition, individual male and female animals also revealed very slight erythema, observed only at 96 h after the 1st injection. All effects had subsided by 144 h p.a. after of the first injection (test day 7).

The macroscopic inspection at necropsy revealed an indurated and/or thickened injection site for all male and female main study animals treated with **30 µg BNT162c1/animal**. In addition, an incrustation was noted at injection site of one male and one female animal.

Recovery period

Very slight (mostly) to severe (very rarely) oedema were still noted for nearly all animals previously treated with **30 µg BNT162c1/animal** during the early recovery period (following the 2nd injection on test day 8). In addition, individual animals also revealed a severe erythema, observed only at 144 h following injection (test day 14). In nearly all male and female animals, all local skin reactions had subsided until test day 16 (i.e. 192 h after the last administration). Only one male animal (no. 162) still presented with reddened skin (scored as severe "erythema" up to test day 24, followed by very slight slight degree up to test day 30) accompanied by an incrusted wound and scar tissue formation. This finding is attributed to test article-associated inflammation at the injection site.

One male animal (no. 179) revealed eschar formation in a skin area on the right leg that was near to but outside the location used for test item injection on test days 18 to 24. This finding is not considered to be related to the test item administration but to be related to the shaving procedure in advance of the start of treatment.

No abnormalities were noted at the injection site(s) at macroscopic inspection at necropsy at the end of the recovery period.

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BNT162b2 - Group 7

Treatment period

Very slight to severe (very rarely) oedema were noted for all animals following the 1st, 2nd, and/or 3rd injection of **100 µg BNT162b2/animal** on test days 1, 8, and/or 15. All oedema noted after the 1st or 2nd injection had subsided by 96 h p.a. after the respective administration.

In addition, a few female animals also revealed very slight erythema following 24 to 96 h following the 1st or 2nd injection. For individual male and female animals, skin reddening (scored as "severe" erythema) was observed only at 144 h after the 2nd injection, but was resolved prior to the 3rd injection.

The macroscopic inspection at necropsy revealed an indurated and/or thickened injection site for 7 of 10 male and 9 of 10 female main study animals treated with **100 µg BNT162b2/animal**.

Recovery period

Very slight (mostly) to moderate (rarely) oedema were still noted for all animals previously treated with **100 µg BNT162b2/animal** during the early part of the recovery period (following the 3rd injection on test day 15). All local skin reactions had subsided by 336 h p.a. (test day 29).

No abnormalities were noted at the injection site(s) at macroscopic inspection at necropsy at the end of the recovery period.

Histopathological examination of injection sites

Treatment period

The histopathological examination revealed test item-related injection site findings in all groups, characterized by mostly moderate inflammation (up to marked) in males and moderate inflammation in females. The most severe findings were noted consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate oedema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. There were no notable injection site findings in control-item administered groups. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac).

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Recovery period

Microscopic findings noted at the injection sites were partially or fully resolved at the end of the 3-week recovery phase. A few inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals.

Microscopic injection site findings correlated with macroscopic findings of thickening, induration, and incrustation.

General observations of local intolerance reactions are given in Table 1-1 (Local tolerance - General observations) and observations of erythema, oedema, indurations, and/or hardenings are listed in Table 1-2 (Local tolerance - Erythema, Oedema, Induration, Hardening).

For detailed listings of histopathological findings at the injection sites, refer to Text table 4-24 (10 or 30 µg BNT162a1/animal, groups 2 and 3), Text table 4-25 (30 or 100 µg BNT162b1/animal, groups 4 and 5), and Text table 4-26 (30 µg BNT162c1/animal, group 6, and 100 µg BNT162b2/animal, group 7).

4.2 Clinical signs

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment and recovery period

None of the male and female animals treated intramuscularly with **10** or **30 µg BNT162a1/animal** (groups 3 and 2), **30** or **100 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** (group 6) on test days 1 and 8 (2 administrations) revealed any test item-related systemic changes in behaviour, external appearance, or consistency of faeces.

A summary of clinical observations is given in Table 2-1 (Clinical Signs - Summary), the individual observations are listed in Table 2-2 (Clinical Signs - Individual Data).

4.3 Mortality

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment and recovery period

No test item-related deaths were noted for any treatment.

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The female animal no. 76 treated with **30 µg BNT162a1/animal** (group 3) and the male animal no. 130 treated with **30 µg BNT162b1/animal** (group 5) died during the blood sampling for dose exposure examination on test day 17 (day of dissection). However, the deaths of these animals are not considered to be test item-related but to be related to the stress caused by the technical procedure of blood withdrawal from the retrobulbar venous plexus under isoflurane anaesthesia after the animals had been fasted overnight.

The macroscopic inspection at necropsy did not reveal any abnormalities for animal no. 76. An enlarged spleen, enlarged adrenal glands, and an enlarged iliac lymph node were noted for animal no. 130. The absolute weight of the spleen was increased by approx. 21% compared to the mean value of the control group. However, these findings are not considered to be sufficient to causally explain the animal's premature death. In summary, the histopathological examination did not reveal a clear cause of death for any of the deceased animals.

As the animals died during terminal anaesthesia, closely before the pending sacrifice, and were dissected immediately after death, the organ weight data from these animals were included into statistical analysis as scheduled.

4.4 Body weight

Mean values per group and individual data of body weight, body weight gain, and body weight at autopsy are listed in Table 3-1 (Body Weight - Summary), Table 3-2 (Body Weight - Individual Data), Table 3-3 (Body Weight Gain-Summary), Table 3-4 (Body Weight Gain - Individual Data), and Table 3-5 (Body Weight at Autopsy).

The mean body weight is plotted in Figure 1-1 (male animals) and Figure 1-2 (female animals) on the following page.

The mean body weight gain for the treatment period from test day 1 to test day 9 (group 6) or test day 16 (groups 1 to 5 and 7) and for the recovery period from test day 10 to test day 30 (group 6) or test day 16 to test day 37 is shown graphically in Figure 1-3 (male animals) and Figure 1-4 (female animals) on page 72.

The body weight at autopsy at terminal sacrifice (test day 9 for group 6, test day 16 for groups 1 to 5 and 7) and at recovery sacrifice (test day 30 for group 6, test day 37 for groups 1 to 5 and 7) is shown graphically in Figure 1-5 (male animals) and Figure 1-6 (female animals) on page 73.

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BNT162a1 - Groups 2 and 3

Treatment period

The body weight of the male animals treated with the high dose of **30 µg BNT162a1/animal** (group 2) on test days 1, 8, and 15 was reduced by up to 16.7% in comparison to the control animals on test days 2, 8/9, and 15/16 (statistically significant at $p \leq 0.01$ as of test day 2). The body weight gain was reduced accordingly by 22 percentage points compared to the control group for the period from test day 1 to test day 16. However, the lowered body weight gain over the whole treatment period is mainly due to the weight loss observed on each day after an administration day. The slope of weight gain increase was the same each time between the day after administration until next dosing compared to the control group. In summary, the absolute body weight was affected, but the body weight gain between dosing was not. Consistent with the lower overall body weight gain, the body weight at autopsy was approx. 17% lower than in the control group on test day 17.

The female animals treated with **30 µg BNT162a1/animal** revealed a slight, but statistically significant (at $p \leq 0.01$ or $p \leq 0.05$) reduction of body weights by up to 7% compared to the control group on test days 9 and 16 (on the respective day after the administrations on test days 8 and 15 in each case). Although changes were not always statistically significant for the female animals, the trend is the same as for the male animals. The body weight gain was approx. 7 percentage points lower than in the control group for the period from test day 1 to test day 16. The body weight at terminal sacrifice (test day 17) was reduced by only approx. 5% compared to the control group indicating some weight re-gain by the end of the dosing period.

The test item-related body weight changes noted for the treatment with **30 µg BNT162a1/animal** are summarised in the text table below.

Text table 4-1: Test item-related body weight changes for BNT162a1

Test item-related changes in mean body weight compared to the control group [%] (refer to Table 3-1)		
Test day	**Group 2: 30 µg BNT162a1/animal**	
	Males	**Females**
2	-6.9**	-4.5
8	-5.6**	None
9	-13.1**	-6.5*
15	-11.5**	-2.6
16	-16.7**	-7.0**

None No test item-related change.

* / ** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

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A body weight increase of up to 19.2% noted for the male animals administered **10 µg BNT162a1/animal** (group 3) in comparison to the control animals on test days 1, 2, and 8 (statistically significant at $p \leq 0.01$) was due to their older age (+6 days) at start of the study (staggered start, refer to Section 2.7). However, the body weight gain from test day 1 to test day 16 was *decreased* compared to the control animals, resulting in slightly lower body weights than in the control group on test day 16. The body weight gain was decreased by approx. 25 percentage points compared to the control group for the period from test day 1 to test day 16.

The female animals treated with **10 µg BNT162a1/animal** (group 3) on test days 1, 8, and 15 revealed a slight decrease of body weight by up to 5.2% in comparison to the control animals on test days 9, 15 and 16. Their body weight gain from test day 1 to test day 16 was only approx. 6 percentage points lower compared to the control group.

The body weight at autopsy was not affected for the male animals and only marginally decreased for the female animals administered **10 µg BNT162a1/animal** (group 3) compared to the control group at terminal sacrifice on test day 17. However, due to the older age slightly higher body weights than in the control group were expected. Therefore, a slight effect on the body weight and the body weight gain due to the treatment with **10 µg BNT162a1/animal** cannot be ruled out completely.

Recovery period

No noteworthy changes were noted for the body weights of the male and female animals previously treated with **10** or **30 µg BNT162a1/animal** (groups 3 and 2) in comparison to the control animals at the end of the recovery period. The body weight gain of the animals was up to approx. 16 percentage points higher compared to the control group for the period from test day 16 to test day 37.

BNT162b1 - Groups 4 and 5

Treatment period

The body weight of the male animals treated with **30 µg BNT162b1/animal** on test days 1, 8, and 15 (group 4) was reduced by up to 8.8% in comparison to the control animals on test day 16 (statistically significant at $p \leq 0.01$). The body weight gain was reduced accordingly by 12 percentage points compared to the control group for the period from test day 1 to test day 16. The body weight at autopsy was 7.3% lower than in the control group on test day 17.

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No noteworthy differences were noted for the body weight, the body weight gain, and the body weight at autopsy between the female animals treated with **30 µg BNT162b1/animal** (group 4) and the control group until the end of the treatment period.

Up to test day 8, the male animals treated with **100 µg BNT162b1/animal** on test days 1, 8, and 15 (group 5) revealed *higher* body weights than the control group animals due to their older age (+6 days compared to the control animals), but a body weight decrease by up to 9.3% compared to the control group as of test day 9 (statistically significant at $p \leq 0.01$ on test days 9 and 16). The body weight gain was reduced by approx. 31 percentage points compared to the control group for the period from test day 1 to test day 16. The body weight at autopsy was approx. 5% lower than in the control group on test day 17.

The female animals treated with **100 µg BNT162b1/animal** revealed a statistically significant (at $p \leq 0.05$) reduction of body weight by 6.1% compared to the control group on test day 9, but there were no noteworthy differences for the body weight, the body weight gain, and the body weight at autopsy in comparison to the control group on test day 17.

The body weight changes that are considered to be related to the treatment with **BNT162b1** are summarised in the text table below.

Text table 4-2: Test item-related body weight changes for BNT162b1

Test item-related changes in mean body weight compared to the control group [%] (refer to Table 3-1)				
Test day	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
2	-4.7**	None	None	-4.7
9	-6.5*	None	-6.6**	-6.1*
15	-5.1*	None	-2.4	None
16	-8.8**	None	-9.3**	-4.5

None No test item-related change.
* / ** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy changes were noted for the body weights of the male and female animals previously treated with **30** or **100 µg BNT162b1/animal** (groups 4 and 5) in comparison to the control animals at the end of the recovery period. The body weight gain of the animals was up to approx. 9 percentage points higher compared to the control group for the period from test day 16 to test day 37.

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BNT162c1 - Group 6

Treatment period

Up to test day 8, the male animals treated with **30 µg BNT162c1/animal** (group 6) revealed body weights that were up to 17% *higher* than in the control group due to their older age (+6 days compared to the control animals). On test day 9, a body weight reduction of 4.3% was noted compared to the control group (not statistically significant at $p \leq 0.01$ or $p \leq 0.05$). No body weight gain was noted for the period from test day 1 to test day 9 whereas the body weight gain in the control group was 21.34% for that period. The body weight at autopsy was approx. 17% lower compared to the control group's body weight at autopsy on test day 10 although the animals in group 6 and in the control group had a comparable age at sacrifice (group 6: 70 days, control group: 71 days).

The female animals treated with **30 µg BNT162c1/animal** revealed a statistically significant (at $p \leq 0.01$) reduction of body weight by 7.0% compared to the control group on test day 9. There was a marginal body weight gain of only approx. 1.5% for the period from test day 1 to test day 9. The body weight at autopsy was approx. 12% lower compared to the control group's body weight at autopsy on test day 10 (the females had the same age as the males, see above).

Recovery period

No noteworthy changes were noted for the body weights of the male and female animals previously treated with **30 µg BNT162c1/animal** in comparison to the control animals at the end of the recovery period. The body weight gain of the animals appeared to be higher compared to the control group for the period from test day 9 to test day 30 (not quantifiable due to the different time course).

BNT162b2 - Group 7

Treatment period

Up to test day 8, the male animals treated with **100 µg BNT162b2/animal** (group 7) revealed body weights that were up to 16% *higher* than in the control group due to their older age (+6 days compared to the control animals). A body weight reduction of up to 11.3% was noted compared to the control group on test days 9, 15, and 16 (statistically significant at $p \leq 0.01$ on test days 9 and 16). There was a body weight gain of only approx. 5% for the period from test day 1 to test day 16, which is approx. 32 percentage points lower compared to the control group. The body weight at autopsy was approx. 8% lower compared to the control group on test day 17.

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The female animals treated with **100 µg BNT162b2/animal** revealed a reduction of body weight by up to 6.8 % compared to the control group starting on test days 2 to 16 (statistically significant at $p \leq 0.01$ or $p \leq 0.05$ on test days 9 and 16). A body weight gain of approx. 6% was noted for the period from test day 1 to test day 16, being approx. 10 percentage points lower compared to the control group. No noteworthy difference was noted for the body weight at autopsy between the females treated with **100 µg BNT162b2/animal** and the females of the control group on test day 17.

Recovery period

No noteworthy changes were noted for the body weight, body weight gain, and body weight at autopsy of the male animals previously treated with **100 µg BNT162b2/animal** in comparison to the control animals at the end of the recovery period. The body weight of the female animals was consistently slightly lower compared to the control group, despite of their older age. The body gain from test day 16 to test day 37 was nearly identical to that of the control group. At the end of the recovery period, there was no noteworthy difference in body weight between the two groups.

Statistically significant differences observed for the body weight between any test item-treated group and the control group as listed in the text table below are not considered to be test item-related but to be coincidental changes.

Text table 4-3: Statistically significant body weight changes considered not test item-related

Body weight changes compared to the control group considered not test item-related (refer to Table 3-1)							
Group	**Test item no.#**	**Dose [µg/animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
3	1	10	m	1	+19.2	$p \leq 0.01$	A
				2	+12.7	$p \leq 0.01$	A
				8	+10.0	$p \leq 0.01$	A
5	3	100	m	1	+17.3	$p \leq 0.01$	A
6	5	30	m	1	+17.0	$p \leq 0.01$	A
				2	+9.1	$p \leq 0.01$	A
7	4	100	m	1	+16.0	$p \leq 0.01$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change is due to the older age of the animals.

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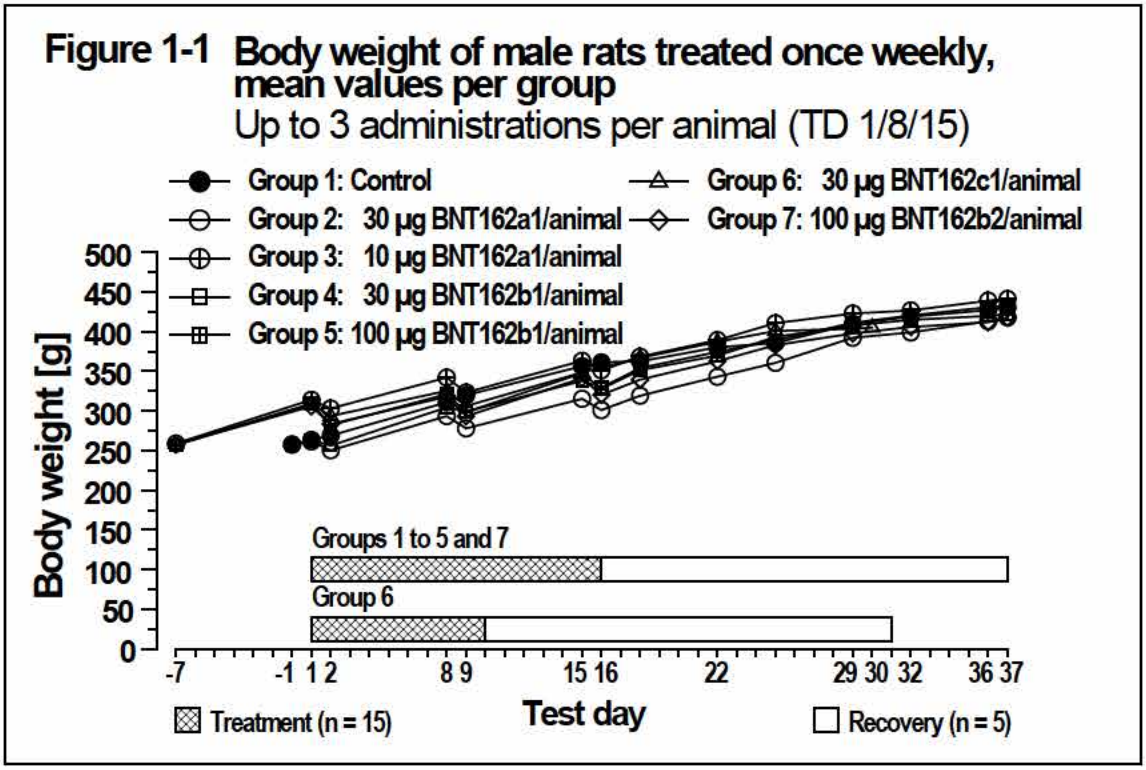

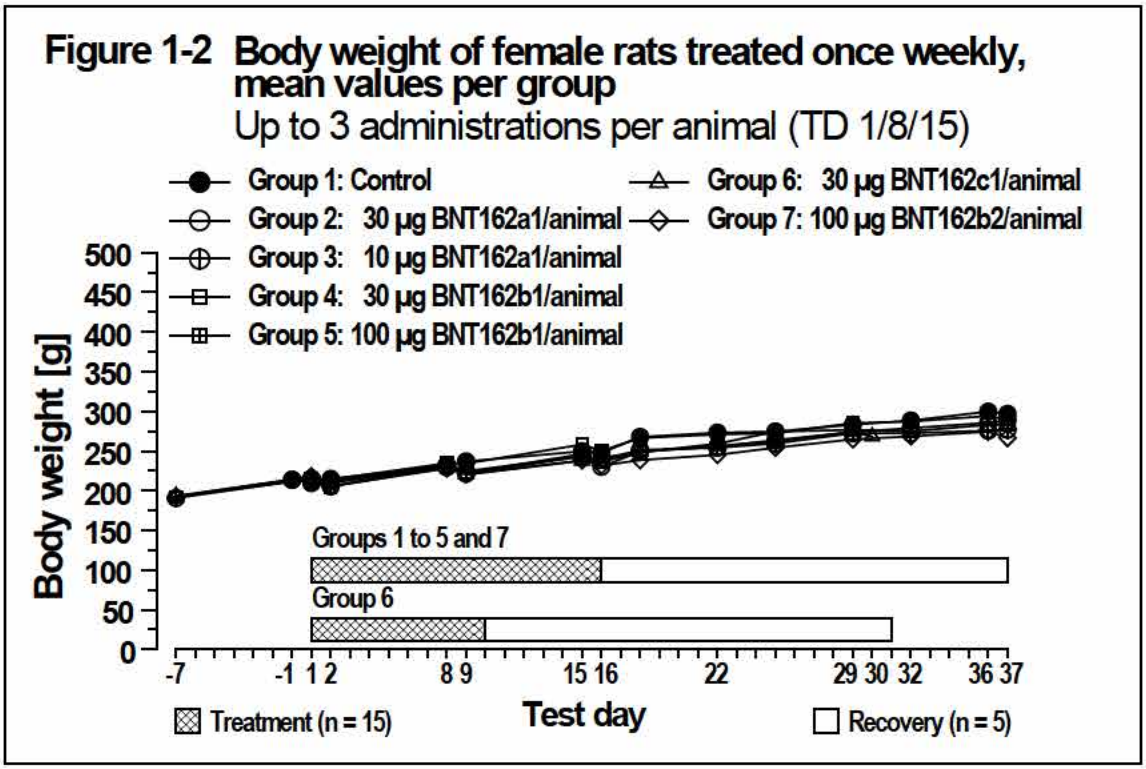

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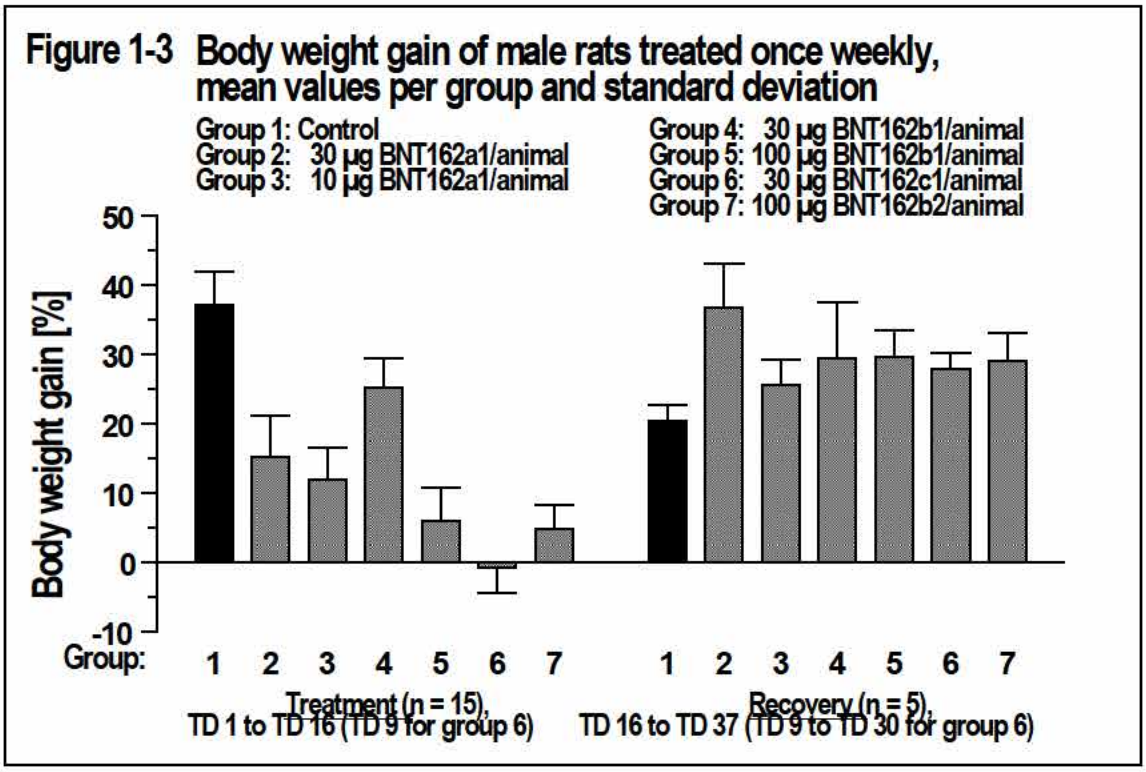

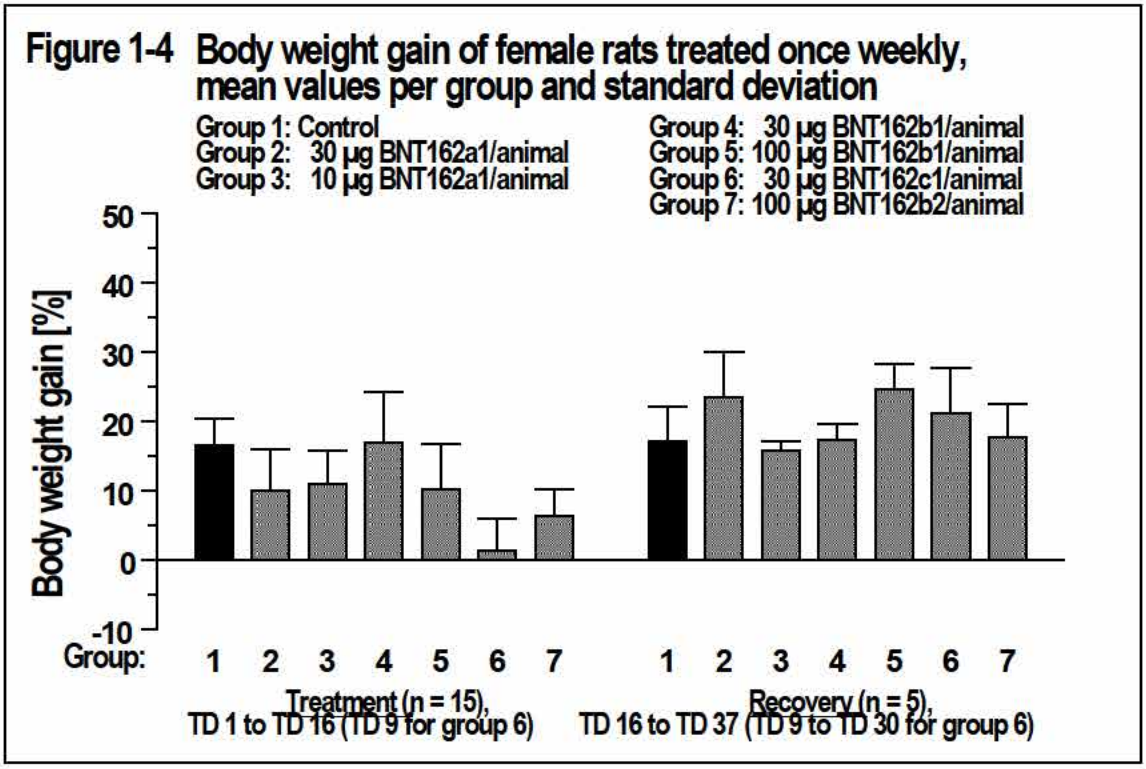

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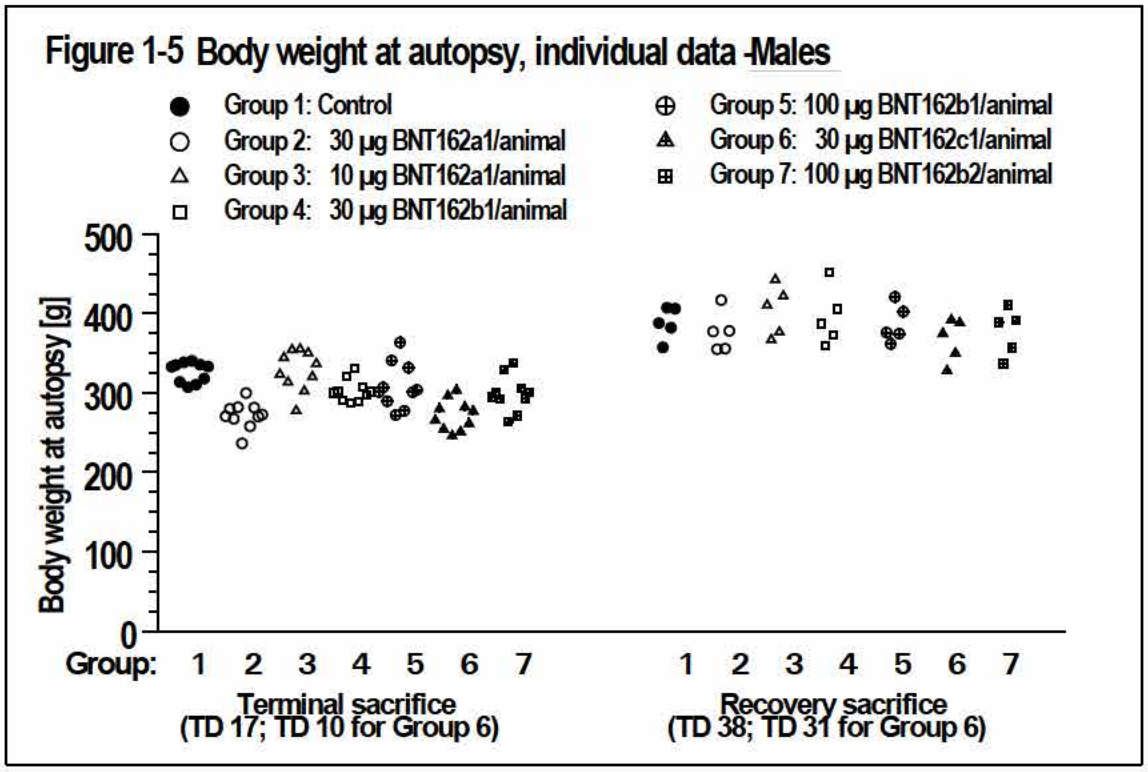

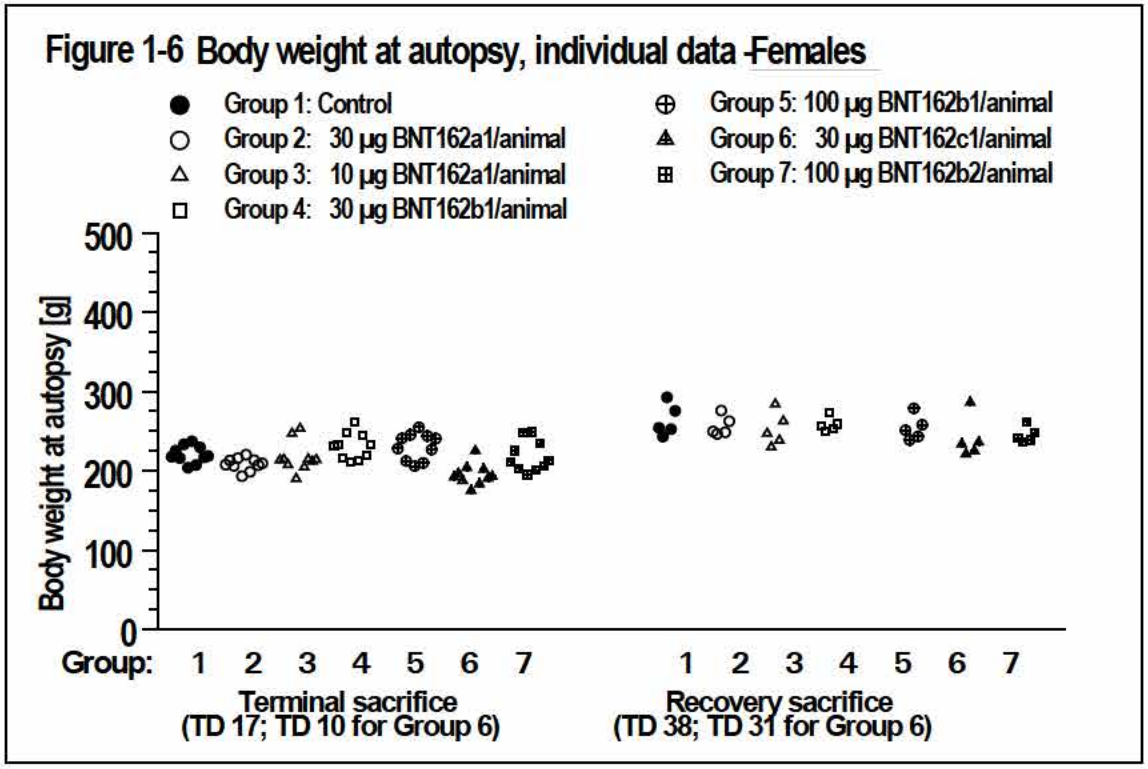

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4.5 Food and drinking water consumption

BNT162a1 - Groups 2 and 3

Treatment period

No test item-related influence was observed on the relative food consumption for the male and female animals following intramuscular treatment with **10 µg BNT162a1/animal** (group 3) on test days 1, 8, and 15 (3 administrations) in comparison to the control.

The relative food consumption of the male animals treated with **30 µg BNT162a1/animal** (group 2) appeared to be slightly decreased by 5.7% in test week 1 and by 7.2% in test week 2 (statistically significant at $p \leq 0.05$ and $p \leq 0.01$). For the female animals of group 2, a slight decrease of the relative food consumption by 3.3% in test week 1 and by 4.4% in test week 2 was observed (not statistically significant). The effect is considered to be test item related.

Recovery period

No noteworthy changes were noted for the relative food consumption of the male and female animals previously treated with **10** or **30 µg BNT162a1/animal** (groups 3 and 2) in comparison to the control animals during the recovery period.

BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery period

No test item-related influence was observed on the relative food consumption for the male and female animals following intramuscular treatment with **10** or **30 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** (group 6) on test days 1 and 8 (2 administrations) in comparison to the control group throughout the treatment and recovery period.

Any differences to the control group are regarded to be within the normal range of biological variation.

The statistically significant differences to the control group's relative food consumption that are not considered to be related to any of the test items are listed in the text table on the following page.

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Text table 4-4: Statistically significant changes in relative food consumption considered not test item-related

Statistically significant changes in relative food consumption (refer to Table 4-1) in comparison to the control group considered not test-item-related							
Group	**Test item no.#**	**Dose [µg/animal]**	**Sex**	**Test week**	**Change [%]**	**Statistical significance**	**Reason**
2	1	30	m	4	+15.6	$p \leq 0.01$	B
				5	+10.7	$p \leq 0.01$	B
3	1	10	m	1	-16.9	$p \leq 0.01$	C
				2	-10.3	$p \leq 0.01$	C
				3	-11.1	$p \leq 0.01$	C
			f	1	-6.5	$p \leq 0.05$	C
5	3	100	m	1	-22.9	$p \leq 0.01$	C
				2	-12.2	$p \leq 0.01$	C
				3	-12.3	$p \leq 0.01$	C
			f	1	-13.3	$p \leq 0.01$	C
				4	+12.6	$p \leq 0.05$	A
6	5	30	m	1	-18.5	$p \leq 0.01$	C
				2	-13.7	$p \leq 0.01$	C
			f	1	-9.7	$p \leq 0.01$	C
7	4	100	m	1	-22.3	$p \leq 0.01$	C
				2	-11.1	$p \leq 0.01$	C
				3	-13.4	$p \leq 0.01$	C
			f	1	-13.7	$p \leq 0.01$	C
				4	+13.2	$p \leq 0.01$	B

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change is within limits of normal biological variation and without toxicological relevance.
B Change is due to the lower weight of the respective animals.
C Change is due to the higher weight of the respective animals.

Visual appraisal of the drinking water consumption did not reveal any noteworthy differences between any of the test item-treated groups and the control group throughout the treatment and recovery period. The consumption was not quantified.

Mean values per group and individual data of food intake are listed in Table 4-1 (Food Consumption - Summary) and Table 4-2 (Food Consumption - Individual Data).

The mean relative food consumption (in g/kg b.w./day) per group and sex is shown graphically in Figure 2-1 (males) and Figure 2-2 (females) on the following page.

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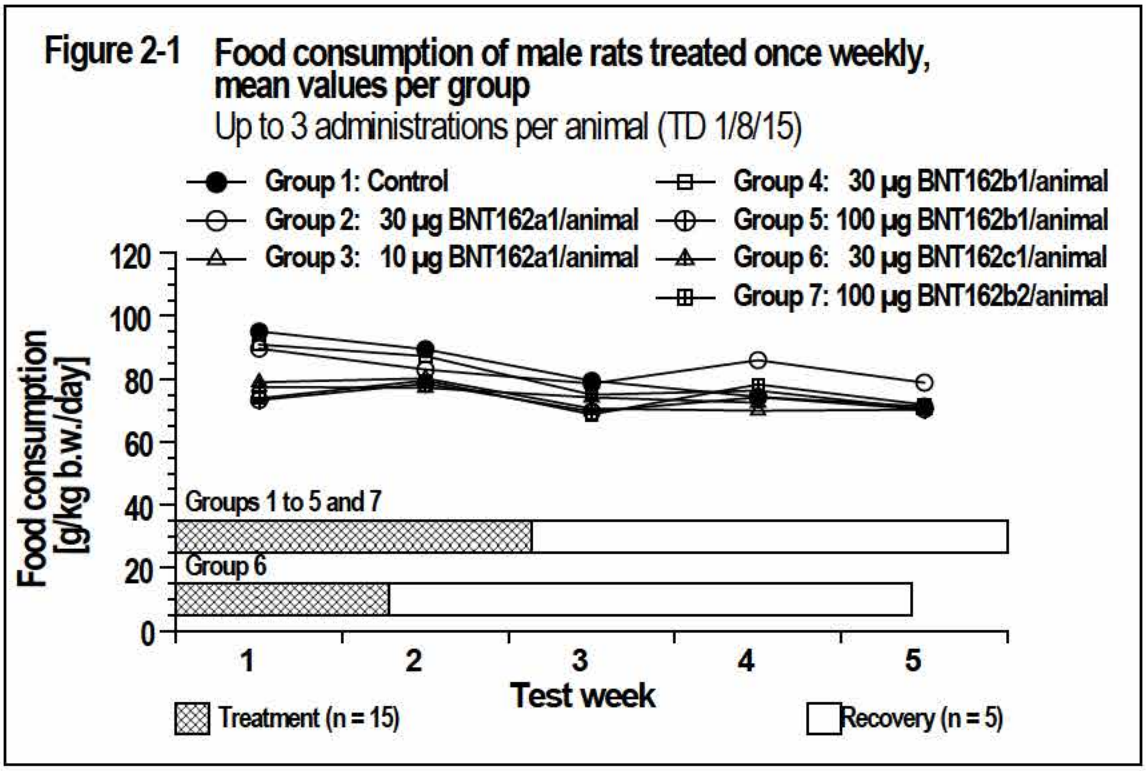

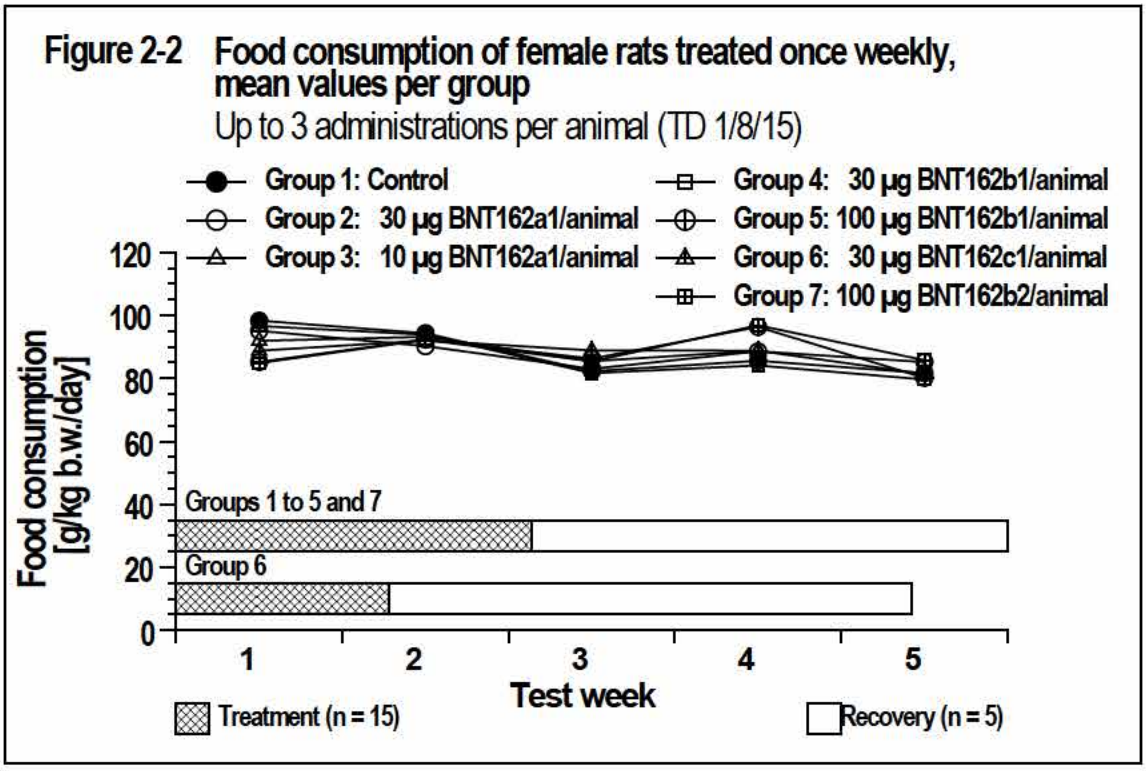

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4.6 Body temperature

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment and recovery period

Intramuscular treatment with **10** or **30 µg BNT162a1/animal** (groups 3 and 2), **30** or **100 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** (group 6) on test days 1 and 8 (2 administrations) led to slightly increased body temperatures at 4 h p.a. and/or 24 h p.a. compared to the control animals (statistically significant at $p \leq 0.01$ or $p \leq 0.05$ in many cases). The effect appeared to be slightly more pronounced in the groups treated with the higher test item dose levels (i.e. groups 2, 5, 6, and 7).

During the recovery period, the body temperature remained at a slightly higher level compared to the control group in all previously test item treated groups.

The slight body temperature *decreases* noted for groups 3, 5, 6, and 7 in comparison to the control group are considered to be due to the circumstances of the time-shift in study conduct for these groups. The body temperature measurements of these animals were performed on dates different from those for the control and by different staff.

Mean values per group and individual data of body temperature are listed in Table 5-1 (Body Temperature - Summary) and Table 5-2 (Body Temperature - Individual Data).

The mean body temperature per group and sex is shown graphically in Figure 3-1 (males) and Figure 3-2 (females) on the following page.

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Figure 3-1 Body temperature of male rats treated once weekly, mean values per group
Up to 3 administrations per animal (TD 1/8/15)

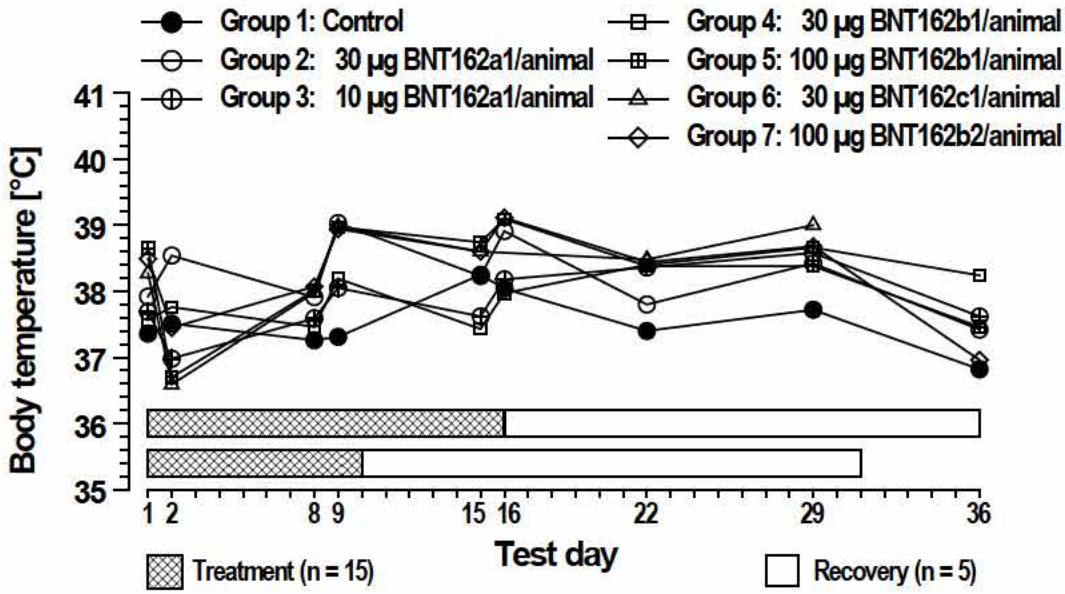
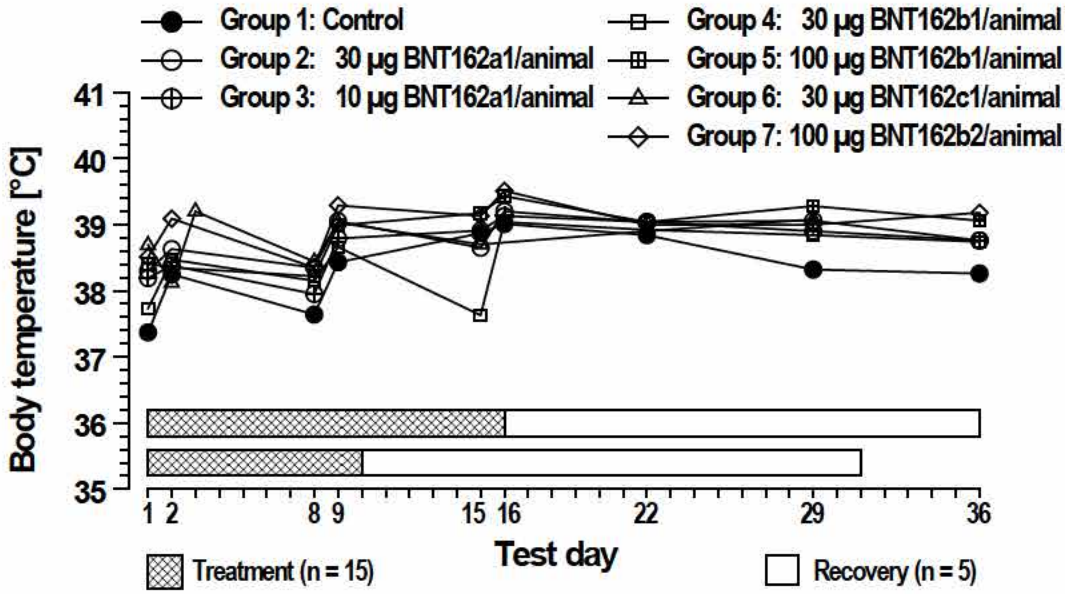


Figure 3-2 Body temperature of female rats treated once weekly, mean values per group
Up to 3 administrations per animal (TD 1/8/15)



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4.7 Haematology and coagulation

The most consistent test item-related haematologic changes were dose-related increases in neutrophils and large unstained cells (LUC), which were seen with all test items on test day 17, but were greatest in groups 2, 5 and 7 and were greater in females relative to males. Other test item-related changes included decreases in the absolute and relative reticulocyte count (test day 4 only), platelet count, and red cell mass (HGB, HCT and RBC; test day 17 only), and increases in the numbers of leucocytes, monocytes, eosinophils, basophils and/or fibrinogen concentrations. All changes were considered to be related to the primary pharmacodynamic activity of the vaccines, which induce a potent immune response.

Increases in fibrinogen levels and leucocytes (most notably neutrophils and LUC), were consistent with an acute phase response secondary to immune activation and inflammation at the injection sites.

Decreases in numbers of reticulocytes, RBC and platelets were associated with increased bone marrow haematopoiesis, consistent with transient, secondary or peripheral effects. Transient reticulocyte decreases (test day 4 only) were likely secondary to the acute phase response and inflammation. Effects on red cell mass were limited to minimal decreases in RBC, HGB, and HCT on test day 17. Platelet decreases were small in magnitude and not expected to result in bleeding. They were likely secondary to inflammation-related platelet activation and consumption. There were no thrombi evident microscopically.

BNT162a1 - Groups 2 and 3

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **10 µg BNT162a1/animal** (group 3) or **30 µg BNT162a1/animal** (group 2) are given in the text table on the following page.

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Text table 4-5: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162a1

Test item-related changes in haematological and coagulation parameters, groups 2 and 3 compared to the control group in % (refer to Table 6-1)				
Parameter	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
Test day 4				
Platelets (PLT)	None	None	None	-22.7**
Reticulocytes (relative)	-64.1**	-52.0**	-75.3**	-62.1**
Reticulocytes (absolute)	-62.1**	-51.5**	-75.6**	-64.4**
Neutrophils (Neut), abs.	None	None	+128.8**	+245.1**
Monocytes (Mono), abs.	None	None	+39.0	+129.5**
Large unclassified cells (LUC), abs.	None	None	+644.9**	+574.7**
Basophils (Baso), abs.	None	None	None	+119.2**
Test day 17				
Haemoglobin (HGB)	None	-7.7**	None	None
Erythrocytes (RBC)	None	-5.4*	None	None
Haematocrit (HCT)	None	-9.7**	None	None
Leucocytes (WBC)	None	None	+79.1**	+104.1**
Platelets (PLT)	-26.1**	-34.6**	-26.1**	-41.7**
Neutrophils (Neut), abs.	+267.1**	+338.0**	+430.6**	+589.4**
Monocytes (Mono), abs.	+103.6**	+131.7**	+84.7*	+97.4*
Large unclassified cells, (LUC) abs.	+455.7**	+520.8**	+1226.1**	+1022.1**
Basophils (Baso), abs.	+130.0**	+105.3*	+110.0**	+215.8**
Fibrinogen	+155.4**	+144.5*	+191.3**	+174.4**

abs. absolute

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **10 µg BNT162a1/animal** (group 3) or **30 µg BNT162a1/animal** (group 2) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

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BNT162b1 - Groups 4 and 5

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, eosinophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **30** or **100 µg BNT162b1/animal** (groups 4 and 5) are given in the text table below.

Text table 4-6: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162b1

Test item-related changes in haematological and coagulation parameters, groups 4 and 5 compared to the control group in % (refer to Table 6-1)				
Parameter	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Test day 4				
Reticulocytes (relative)	-43.0	None	-65.6**	-42.6**
Reticulocytes (absolute)	-44.3**	None	-63.3**	-42.6**
Large unclassified cells (LUC), abs.	None	None	None	+250.6**
Test day 17				
Haemoglobin (HGB)	None	-10.5**	-10.9**	-13.5**
Erythrocytes (RBC)	None	-8.2**	-5.6	-9.5**
Haematocrit (HCT)	None	-9.1**	-13.9**	-14.7**
Leucocytes (WBC)	None	+79.3**	+82.2**	+102.7**
Platelets (PLT)	None	None	-25.0**	-34.4**
Neutrophils (Neut), abs.	+304.2**	+486.1**	+447.3**	+636.3**
Monocytes (Mono), abs.	+102.3**	+134.4**	+77.9*	+113.8**
Eosinophils (Eos), abs.	+111.9**	+227.7**	+230.3**	+440.4**
Large unclassified cells (LUC), abs.	+169.3**	+457.1**	+575.0**	+714.3**
Basophils (Baso), abs.	+100.0**	+121.1**	+110.0**	+126.3**
Fibrinogen	+155.7**	+146.2**	+192.1**	+161.4**

abs. absolute

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

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Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **30** or **100 µg BNT162b1/animal** (groups 4 and 5) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

BNT162c1 - Group 6

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **30 µg BNT162c1/animal** (group 6) are given in the text table below.

Text table 4-7: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162c1

Test item-related changes in haematological and coagulation parameters, group 6 compared to the control group in % (refer to Table 6-1)		
Parameter	**Group 6: 30 µg BNT162c1/animal**	
	Males	**Females**
Test day 4		
Reticulocytes (relative)	-76.5**	-59.0**
Reticulocytes (absolute)	-74.9**	-59.3**
Neutrophils (Neut), abs.	+68.4**	+104.9**
Monocytes (Mono), abs.	+38.7	+93.7**
Large unclassified cells (LUC), abs.	+360.7**	+283.9**
Basophils (Baso), abs.	+130.8**	None

- Text table continued on the next page -

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Test item-related changes in haematological and coagulation parameters, group 6 compared to the control group in % (refer to Table 6-1)		
Parameter	**Group 6: 30 µg BNT162c1/animal**	
	Males	**Females**
- Text table continued from previous page -		
Test day 10		
Haemoglobin (HGB)	None	↓
Erythrocytes (RBC)	None	↓
Haematocrit (HCT)	None	↓
Leucocytes (WBC)	↑	↑
Platelets (PLT)	↓	↓
Neutrophils (Neut), abs.	↑	↑
Monocytes (Mono), abs.	↑	↑
Large unclassified cells (LUC), abs.	↑	↑

abs. absolute

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

↓ Decrease relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **30 µg BNT162c1/animal** (group 6) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

BNT162b2 - Group 7

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, eosinophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **100 µg BNT162b2/animal** (group 7) as given in the text table on the following page.

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Text table 4-8: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162b2

Test item-related changes in haematological and coagulation parameters, group 7 compared to the control group in % (refer to Table 6-1)		
Parameter	**Group 7: 100 µg BNT162b2/animal**	
	Males	**Females**
Test day 4		
Reticulocytes (relative)	-74.3**	-47.7**
Reticulocytes (absolute)	-72.1**	-48.2**
Large unclassified cells (LUC), abs.	+295.5**	+319.5**
Basophils (Baso), abs.	+150.0**	None
Test day 17		
Haemoglobin (HGB)	-9.1**	-12.7**
Erythrocytes (RBC)	None	-9.8**
Haematocrit (HCT)	-11.9**	-13.5**
Leucocytes (WBC)	+118.7**	+111.0**
Platelets (PLT)	-29.2**	-34.1**
Neutrophils (Neut), abs.	+605.8**	+679.8**
Eosinophils (Eos), abs.	+419.3**	+509.6**
Large unclassified cells, (LUC) abs.	+685.2**	+594.8**
Basophils (Baso), abs.	+146.7**	+105.3*
Fibrinogen	+205.2**	+160.2**

abs. absolute

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **100 µg BNT162b2/animal** (group 7) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

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No test item-related effects were observed for the the numbers of lymphocytes, the prothrombin time (PT), the activated partial thromboplastin time (aPTT), the mean corpuscular volume (MCV), the mean corpuscular haemoglobin (MCH), the mean corpuscular haemoglobin concentration (MCHC), the mean platelet (thrombocyte) volume (MPV), the relative volume of thrombocytes / Plateletcrit (PCT), the platelet distribution width (PDW), the red cell distribution width (RDW), and the mean platelet component (MPC) for any of the test items during the treatment period and at the end of the recovery period. All data of the parameters given before are considered to be within the normal range of biological variability.

Statistically significant differences in haematological and coagulation parameters noted in comparison to the control group during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental are listed in the text table starting below.

Text table 4-9: Statistically significant differences in haematological and coagulation parameters considered not test item-related

Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Haemoglobin content (HGB)	2	1	30	m	17	-5.1	$p \leq 0.01$	A
	3	1	10	m	4	+4.5	$p \leq 0.05$	A
					17	-4.9	$p \leq 0.01$	A
	4	3	30	m	4	-4.5	$p \leq 0.05$	A
					17	-5.7	$p \leq 0.01$	A
	5	3	100	m	4	+3.8	$p \leq 0.05$	A
	6	5	30	m	4	+4.1	$p \leq 0.05$	A
	7	4	100	m	4	+5.9	$p \leq 0.01$	A
Erythrocytes (RBC)	3	1	10	m	4	+6.7	$p \leq 0.01$	A
	5	3	100	m	4	+7.1	$p \leq 0.01$	A
	6	5	30	m	4	+7.2	$p \leq 0.01$	A
	7	4	100	m	4	+8.0	$p \leq 0.01$	A
Leucocytes (WBC)	2	1	30	f	4	+53.2	$p \leq 0.01$	A
	3	1	10	m	17	+62.4	$p \leq 0.01$	A
				f	17	+55.0	$p \leq 0.05$	A
	4	3	30	m	17	+60.7	$p \leq 0.01$	A
	6	5	30	m	4	+37.6	$p \leq 0.01$	A
	7	4	100	m	4	+37.0	$p \leq 0.01$	A

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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Reticulocytes (rel.)	2	1	30	m	17	-23.6	$p \leq 0.01$	A
	4	3	30	f	4	-25.0	$p \leq 0.01$	A
	7	4	100	m	17	-23.3	$p \leq 0.01$	A
Reticulocytes (abs.)	2	1	30	m	17	-25.5	$p \leq 0.01$	A
	3	1	10	m	17	-18.8	$p \leq 0.05$	A
	4	3	30	m	17	-19.6	$p \leq 0.05$	A
				f	4	-26.5	$p \leq 0.05$	A
	7	4	100	m		-26.3	$p \leq 0.01$	A
Platelets (PLT)	4	3	30	f	17	-17.9	$p \leq 0.01$	A
Haematocrit value (HCT)	2	1	30	m	17	-5.8	$p \leq 0.01$	A
	3	1	10	m	17	-8.7	$p \leq 0.01$	A
	4	3	30	m	4	-3.6	$p \leq 0.05$	A
					17	-5.3	$p \leq 0.01$	A
Neutrophils (Neut), abs.	7	4	100	f	4	+126.9	$p \leq 0.01$	A
Lymphocytes (Lym), abs.	6	5	30	m	4	+28.0	$p \leq 0.05$	A
	7	4	100	m	4	+36.8	$p \leq 0.01$	A
Eosinophils (Eos), abs.	3	1	10	f	17	+61.7	$p \leq 0.05$	A
Large unclassified cells (LUC), abs.	3	1	10	m	4	+146.1	$p \leq 0.01$	A
				f	4	+113.8	$p \leq 0.01$	A
	5	3	100	m	4	+151.7	$p \leq 0.01$	A
Basophils (Baso), abs.	3	1	10	m	4	+80.8	$p \leq 0.05$	A
	7	4	100	f	4	+65.4	$p \leq 0.05$	A
Activated partial thromboplastin time (aPTT)	2	1	30	m	17	+15.5	$p \leq 0.01$	A
				f	17	+16.6	$p \leq 0.01$	A
	3	1	10	m	17	+18.2	$p \leq 0.01$	A
				f	17	+23.3	$p \leq 0.01$	A
	5	3	100	f	17	+13.7	$p \leq 0.01$	A
	7	4	100	m	17	+14.1	$p \leq 0.05$	A
				f	17	+18.1	$p \leq 0.01$	A
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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Mean corpuscular volume (MCV)	2	1	30	m	17	-2.9	$p \leq 0.05$	A
	3	1	10	m	4	-4.4	$p \leq 0.01$	A
					17	-7.3	$p \leq 0.01$	A
				f	17	-4.5	$p \leq 0.01$	A
	4	3	30	m	17	-2.7	$p \leq 0.05$	A
	5	3	100	m	4	-5.4	$p \leq 0.01$	A
					17	-8.7	$p \leq 0.01$	A
				f	17	-5.8	$p \leq 0.01$	A
	6	5	30	m	4	-5.2	$p \leq 0.01$	A
	7	4	100	m	4	-5.3	$p \leq 0.01$	A
					17	-8.6	$p \leq 0.01$	A
				f	17	-4.0	$p \leq 0.05$	A
Mean corpuscular haemoglobin (MCH)	3	1	10	m	17	-3.6	$p \leq 0.01$	A
	4	3	30	m	17	-3.3	$p \leq 0.01$	A
	5	3	100	m	17	-5.7	$p \leq 0.01$	A
				f	17	-4.3	$p \leq 0.01$	A
	7	4	100	m	17	-6.0	$p \leq 0.01$	A
Mean corpuscular haemoglobin concentration (MCHC)	2	1	30	m	4	+1.4	$p \leq 0.05$	A
	3	1	10	m	4	+2.7	$p \leq 0.01$	A
					17	+4.1	$p \leq 0.01$	A
				f	4	+2.0	$p \leq 0.01$	A
					17	+2.1	$p \leq 0.01$	A
	4	3	30	f	17	-1.6	$p \leq 0.05$	A
	5	3	100	m	4	+2.7	$p \leq 0.01$	A
					17	+3.3	$p \leq 0.01$	A
				f	17	+1.6	$p \leq 0.05$	A
	6	5	30	m	4	+2.4	$p \leq 0.01$	A
				f	4	+2.6	$p \leq 0.01$	A
	7	4	100	m	4	+3.7	$p \leq 0.01$	A
					17	+3.2	$p \leq 0.01$	A
				f	4	+3.0	$p \leq 0.01$	A

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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Mean platelet (thrombocyte) volume (MPV)	3	1	10	m	17	-20.4	p ≤ 0.01	A
				f	4	-11.1	p ≤ 0.01	A
					17	-17.2	p ≤ 0.01	A
	5	3	100	m	17	-17.1	p ≤ 0.01	A
				f	4	-8.1	p ≤ 0.05	A
					17	-13.4	p ≤ 0.01	A
	6	5	30	f	4	-7.6	p ≤ 0.05	A
	7	4	100	m	17	-14.2	p ≤ 0.01	A
				f	17	-11.6	p ≤ 0.01	A
Relative volume of thrombocytes / Plateletcrit (PCT)	2	1	30	m	17	-20.3	p ≤ 0.01	A, B
				f	4	-18.2	p ≤ 0.05	A
					17	-36.6	p ≤ 0.01	A, B
	3	1	10	m	17	-41.5	p ≤ 0.01	A, B
				f	17	-46.5	p ≤ 0.01	A, B
	4	3	30	f	17	-20.1	p ≤ 0.01	A, B
	5	3	100	m	17	-37.9	p ≤ 0.01	A, B
				f	17	-43.4	p ≤ 0.01	A, B
	7	4	100	m	17	-38.7	p ≤ 0.01	A, B
				f	17	-43.2	p ≤ 0.01	A, B
Platelet distribution width (PDW)	2	1	30	m	4	+25.1	p ≤ 0.01	A
					17	+25.3	p ≤ 0.01	A, B
				f	17	+21.0	p ≤ 0.01	A, B
	3	1	10	m	4	+17.4	p ≤ 0.01	A
					17	+50.0	p ≤ 0.01	A, B
				f	17	+46.1	p ≤ 0.01	A, B
	4	3	30	m	17	+8.5	p ≤ 0.05	A, B
	5	3	100	m	4	+14.0	p ≤ 0.05	A
					17	+47.1	p ≤ 0.01	A, B
				f	17	+48.8	p ≤ 0.01	A, B
	6	5	30	m	4	+23.3	p ≤ 0.01	A
	7	4	100	m	4	+24.7	p ≤ 0.01	A
					17	+45.8	p ≤ 0.01	A, B
				f	17	+42.4	p ≤ 0.01	A, B
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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Red cell distribution width (RDW)	2	1	30	m	4	+6.2	p ≤ 0.01	A
					17	+7.3	p ≤ 0.01	A
					38	+17.7	p ≤ 0.01	A, B
				f	17	+11.1	p ≤ 0.01	A
					38	+14.9	p ≤ 0.01	A, B
	3	1	10	m	17	-12.2	p ≤ 0.01	A
					38	+18.8	p ≤ 0.01	A, B
				f	17	-8.7	p ≤ 0.01	A
					38	+12.9	p ≤ 0.01	A, B
	4	3	30	m	17	+8.9	p ≤ 0.01	A
					38	+16.9	p ≤ 0.01	A, B
				f	17	+6.1	p ≤ 0.05	A
					38	+12.4	p ≤ 0.05	A, B
	5	3	100	m	17	-12.2	p ≤ 0.01	A
					38	+16.0	p ≤ 0.01	A, B
				f	17	-6.7	p ≤ 0.05	A
					38	+14.8	p ≤ 0.01	A, B
	7	4	100	m	17	-12.0	p ≤ 0.01	A
					38	+15.3	p ≤ 0.01	A, B
				f	17	-6.2	p ≤ 0.05	A
					38	+14.8	p ≤ 0.01	A, B
Mean platelet component (MPC)	2	1	30	m	4	+10.1	p ≤ 0.01	A
					17	+9.1	p ≤ 0.01	A, B
				f	17	+11.0	p ≤ 0.01	A, B
	3	1	10	m	4	+13.5	p ≤ 0.01	A
					17	+17.2	p ≤ 0.01	A, B
				f	4	+12.5	p ≤ 0.01	A
					17	+14.5	p ≤ 0.01	A, B
					38	+9.5	p ≤ 0.05	A
	4	3	30	f	17	+8.8	p ≤ 0.01	A, B
- Text table continued on the next page -								

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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Mean platelet component (MPC) *- continued*	5	3	100	m	4	+13.0	$p \leq 0.01$	A
					17	+19.5	$p \leq 0.01$	A, B
				f	4	+14.3	$p \leq 0.01$	A
					17	+20.2	$p \leq 0.01$	A, B
					38	+12.7	$p \leq 0.01$	A
	6	5	30	m	4	+14.0	$p \leq 0.01$	A, B
				f	4	+11.8	$p \leq 0.01$	A
	7	4	100	m	4	+15.8	$p \leq 0.01$	A
					17	+18.7	$p \leq 0.01$	A, B
				f	4	+14.8	$p \leq 0.01$	A
					17	+18.3	$p \leq 0.01$	A, B
					38	+14.4	$p \leq 0.01$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

abs. absolute count
rel. relative count

A Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
B Change is due to the relative high or low value noted for the control group.

Group mean values of haematological and coagulation parameters are presented in Table 6-1 (Haematological Parameters - Summary), individual data are listed in Table 6-2 (Haematological Parameters - Individual Data).

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4.8 Clinical chemistry

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period

An elevated plasma activity of gamma-glutamyltransferase (gamma-GT) was noted for all test item-treated groups in comparison to the control group as given in the text table below. There were no macroscopic or microscopic findings (see Section 4.14 and Section 4.16) consistent with cholestasis or hepatobiliary injury to explain the increased gamma-GT.

Text table 4-10: Test item-related changes in plasma activity of gamma-glutamyltransferase

Test item-related changes in plasma activity of gamma-glutamyltransferase (gamma-GT) compared to the control group in % (refer to Table 7-1)								
Test day	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
4	+208.4**	+212.5**	+343.2**	+317.0**	+165.3**	+163.6	+249.5**	+322.7**
17	+87.7**	+174.4**	+173.5**	+228.1**	+121.6**	+225.6**	+158.0**	+263.6**
Test day	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
4	+278.9**		+328.4**		+242.1**		+355.7**	
10	↑		↑					
17					+198.1**		+317.4**	

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

The range of individual data noted for the gamma-GT activity in several test groups slightly exceeded the range of **LPT**'s historical data as summarised in the text table on the following page.

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Text table 4-11: Comparison of gamma-glutamyltransferase activity observed in this study to **LPT**'s historical data

Enzyme activity of gamma-glutamyltransferase (gamma-GT) [U/mL plasma]					
Sex	**Group**	**Data observed in this study[#1] Mean (Range of individual data)**			**LPT historical Data[#2] Mean (Range of individual data)**
		TD 4	**TD 10[#3]/17**	**TD 31[#3]/38**	
Males	1	0.95 (0.1 - 2.4)	1.62 (0.7 - 2.9)	2.60 (1.6 - 3.6)	2.28 (0.4 - 5.1)
	2	4.21 (2.6 - 5.6)	4.43 (3.2 - 5.6)	2.74 (2.5 - 3.5)	
	3	2.93 (1.8 - 3.6)	3.04 (1.5 - 4.5)	1.88 (1.1 - 2.6)	
	4	2.52 (1.4 - 3.1)	3.59 (2.9 - 4.5)	2.30 (1.6 - 3.0)	
	5	3.52 (2.4 - 4.4)	4.18 (2.8 - 6.0)	1.34 (0.3 - 2.3)	
	6	3.60 (1.4 - 5.2)	3.98 (2.8 - 6.1)	1.84 (1.2 - 2.3)	
	7	3.25 (1.3 - 4.9)	4.83 (3.6 - 6.5)	1.82 (0.5 - 3.2)	
Females	1	0.88 (0.1 - 1.9)	1.21 (0.6 - 2.4)	2.48 (1.2 - 3.0)	2.43 (0.2 - 4.8)
	2	3.67 (1.6 - 5.4)	3.97 (2.9 - 4.7)	3.06 (1.9 - 3.4)	
	3	2.75 (1.6 - 3.4)	3.32 (1.1 - 5.4)	1.74 (0.5 - 2.8)	
	4	2.32 (0.7 - 4.7)	3.94 (2.3 - 6.0)	2.52 (1.4 - 3.2)	
	5	3.72 (1.3 - 5.8)	4.40 (3.7 - 5.2)	2.12 (1.6 - 3.2)	
	6	3.77 (2.4 - 4.7)	4.26 (3.0 - 5.4)	2.14 (1.8 - 2.5)	
	7	4.01 (3.2 - 5.9)	5.05 (4.5 - 6.4)	2.44 (1.8 - 3.5)	

[#1] Age of animals:
Groups 1, 2, and 4: 57 days on test day 4, 70 days on test day 17, 91 days on test day 38.
Groups 3, 5, and 7: 63 days on test day 4, 76 days on test day 17, 97 days on test day 38.
Group 6: 63 days on test day 4, 69 days on test day 10, 90 days on test day 31.

[#2] Obtained from 3 studies conducted at **LPT** from 2016 to 2018 (in total 45 control group animals per sex, age at examination: 30 to 92 days, treated only with physiological saline or vehicle). The data were not audited by **LPT**'s QAU.

[#3] Group 6 only (main study dissection: test day 10, recovery dissection: test day 31).

TD Test day

A graphical presentation of the gamma-glutamyltransferase activity is given in Figure 4-1 (males) and Figure 4-2 (females) on the following page.

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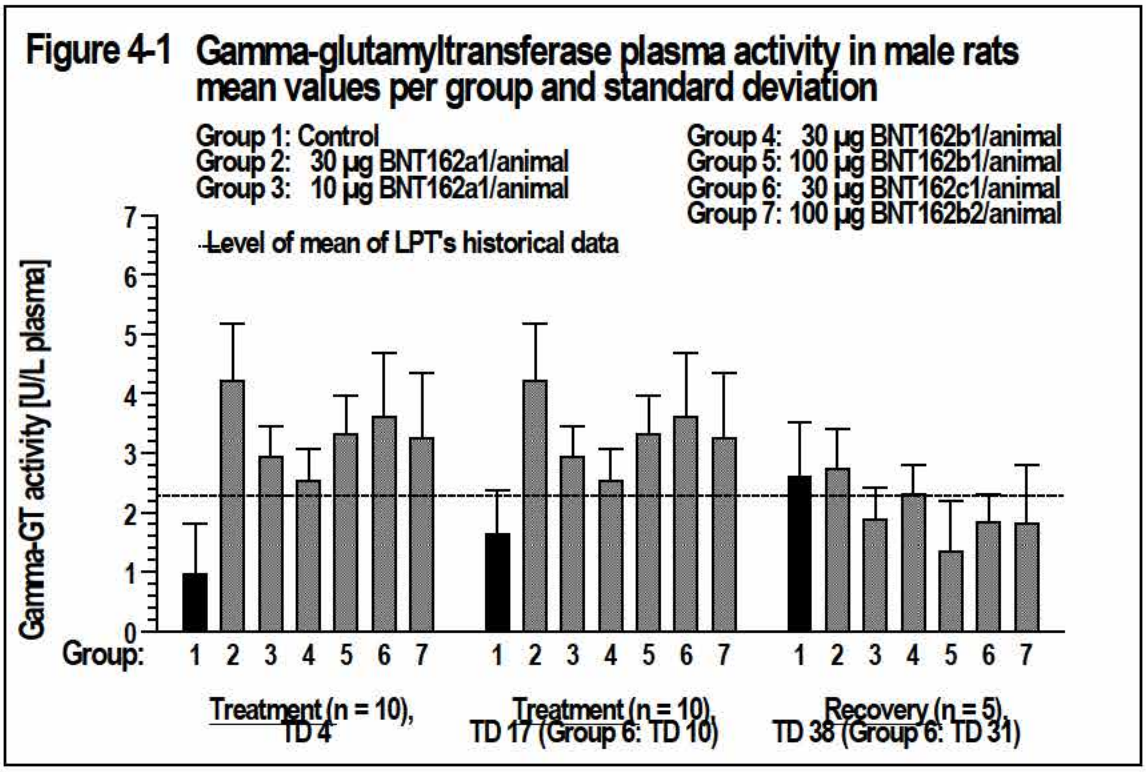

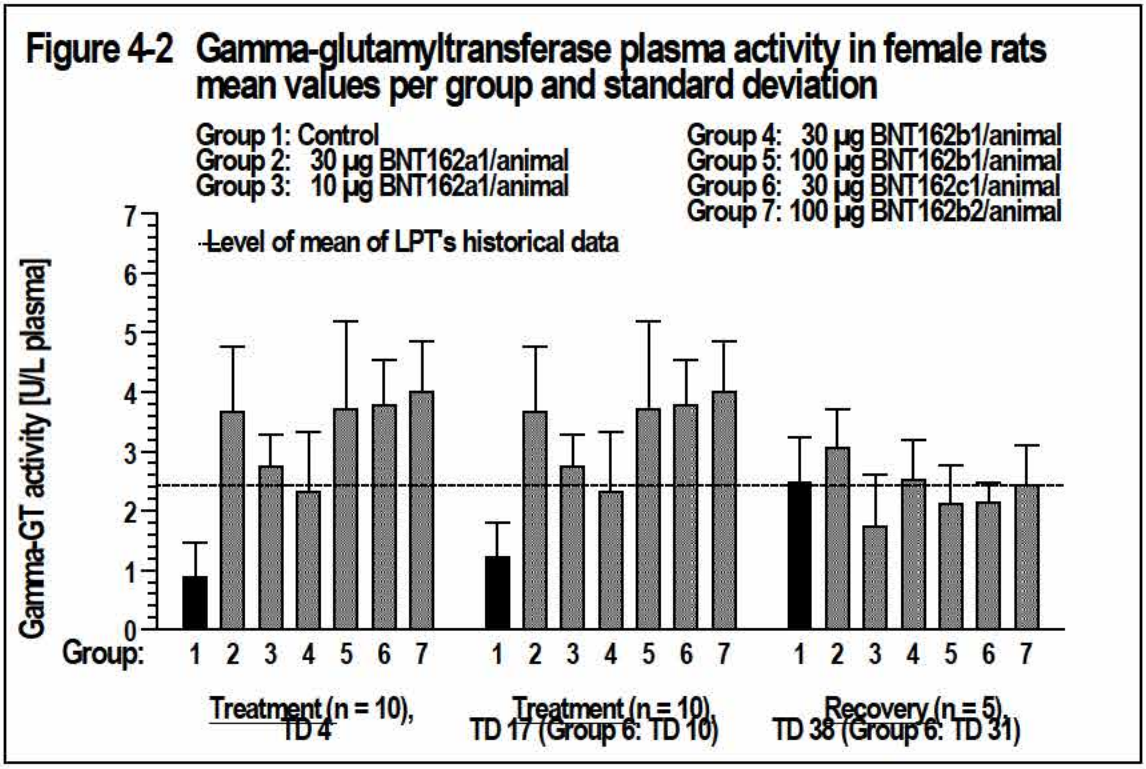

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The elevated plasma activity of gamma-glutamyltransferase is considered to be related to the test item administration, but the cause is unclear.

Further, a decrease in albumin plasma levels and an increase in globulin plasma levels, resulting in an altered albumin/globulin ratio, were observed in all test item treated groups. The changes are consistent with an acute phase response in albumin and globulin where albumin goes down and globulin goes up with inflammation, and the albumin/globulin ratio decreases. The statistically significant changes noted in albumin and globulin levels and the alb./glob. ratio are listed in the text table below.

Text table 4-12: Statistically significant differences in albumin and globulin levels and the albumin/globulin ratio

Statistically significant differences in albumin and globulin levels and the albumin/ globulin ratio compared to the control group (refer to Table 7-1)						
Parameter	**Group**	**Test item**	**Dose [µg/animal]**	**Sex**	**Test day**	**Change [%]**
Albumin	2	BNT162a1	30	m	4	-9.4**
					17	-5.5**
				f	4	-14.1**
					17	-8.8**
	3	BNT162a1	10	m	4	-6.8**
					17	-5.9**
				f	4	-11.3**
					17	-8.8**
	4	BNT162b1	30	m	4	-4.1**
					17	-3.9**
				f	4	-8.4*
					17	-9.8**
	5	BNT162b1	100	m	4	-7.0**
					17	-3.8**
				f	4	-10.8**
					17	-10.5**
	6	BNT162c1	30	m	4	-7.7**
				f	4	-11.7**
	7	BNT162b2	100	m	4	-9.1**
					17	-5.9**
				f	4	-12.6**
					17	-11.0**
Globulin	2	BNT162a1	30	m	4	+9.5**
					17	+9.7**
				f	17	+13.6**

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Statistically significant differences in albumin and globulin levels and the albumin/ globulin ratio compared to the control group (refer to Table 7-1)						
Parameter	**Group**	**Test item**	**Dose [µg/animal]**	**Sex**	**Test day**	**Change [%]**
- Text table continued from previous page -						
Globulin *- continued*	4	BNT162b1	30	m	4	+15.9**
					17	+18.6**
				f	4	+9.5*
					17	+17.9**
	5	BNT162b1	100	m	4	+9.1**
					17	+26.3**
				f	17	+14.4**
	6	BNT162c1	30	m	4	+6.5*
	7	BNT162b2	100	m	4	+7.3*
					17	+23.1**
				f	17	+17.7**
Albumin/Globulin Ratio	2	BNT162a1	30	m	4	-17.1**
					17	-13.9**
				f	4	-18.0**
					17	-19.3**
	3	BNT162a1	10	m	4	-8.4**
					17	-11.7**
	4	BNT162b1	30	m	4	-17.1**
					17	-18.9**
				f	4	-16.3**
					17	-23.6**
	5	BNT162b1	100	m	4	-14.6**
					17	-23.8**
				f	4	-17.0**
					17	-21.7**
	6	BNT162c1	30	m	4	-13.2**
				f	4	-10.1**
	7	BNT162b2	100	m	4	-15.1**
					17	-23.6**
				f	4	-15.7**
					17	-24.4**

m male
f female
*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

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No other test item-related influence was observed on any of the biochemical parameters for the animals treated with **10** or **30 µg BNT162a1/animal** (groups 3 and 2), **30** or **100 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15, or with **30 µg** BNT162c1/**animal** (group 6) on test days 1 and 8 compared to the control animals during the treatment period (test day 4, and test day 10 for group 6/test day 17 for groups 1 to 5 and 7) and at the end of the recovery period.

Recovery period

The elevated plasma activity of gamma-glutamyltransferase noted during the treatment period had subsided in all test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups) and was in a range comparable to that of the control group.

No test item-related effects were noted on the plasma levels of total bilirubin, total cholesterol, creatinine, glucose, phosphate, total protein, urea (in blood), triglycerides, calcium, chloride, potassium, and sodium. No test item related influence was noted on the plasma enzyme activities of alanine aminotransferase (ALAT), alkaline phosphatase (aP), aspartate aminotransferase (ASAT), lactate dehydrogenase (LDH), and creatine kinase (CK). All data of the parameters given above are considered to be within the range of normal biological variability throughout the treatment and recovery period.

Statistically significant differences (at $p \leq 0.01$ or $p \leq 0.05$) were noted for several clinical chemistry parameters between the various test item-treated groups and the control group. The majority of the changes noted were of only marginal degree and occurred in groups 3, 5, 6, and 7, for the animals of which the study conduct started at a later time (see Section 2.7). These animals were 6 days older than the control animals at the time of examination. Blood withdrawal and plasma analysis were performed on dates different from those for the control. An influence of this time offset on the analyses' results cannot be completely excluded.

Statistically significant differences in clinical chemistry parameters in comparison to the control group during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental are listed in the text table on the following page.

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Text table 4-13: Statistically significant differences in clinical chemistry parameters considered not test item-related

Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Globulin	3	1	10	f	38	-19.3	$p \leq 0.01$	A
Albumin/Globulin Ratio	3	1	10	f	38	+18.2	$p \leq 0.01$	A
Bilirubin	2	1	30	m	17	+40.3	$p \leq 0.01$	A
				f	17	+33.3	$p \leq 0.01$	A
	3	1	10	m	4	-26.7	$p \leq 0.01$	A
					17	+31.5	$p \leq 0.01$	A
				f	4	-20.5	$p \leq 0.05$	A
	4	3	30	f	4	-26.8	$p \leq 0.01$	A
	5	3	100	m	4	-27.2	$p \leq 0.01$	A
					17	+46.2	$p \leq 0.01$	A
				f	4	-21.1	$p \leq 0.01$	A
					17	+26.4	$p \leq 0.05$	A
	6	5	30	m	4	-28.8	$p \leq 0.01$	A
	7	4	100	m	4	-25.1	$p \leq 0.01$	A
					17	+42.9	$p \leq 0.01$	A
				f	4	-22.2	$p \leq 0.01$	A
					17	+30.7	$p \leq 0.01$	A
Cholesterol	2	1	30	m	4	-18.7	$p \leq 0.05$	A
					17	-37.5	$p \leq 0.01$	A
	3	1	10	m	17	-21.6	$p \leq 0.05$	A
	4	3	30	m	17	-40.1	$p \leq 0.01$	A
	5	3	100	m	4	-26.4	$p \leq 0.01$	A
					17	-31.5	$p \leq 0.01$	A
	6	5	30	m	4	-19.4	$p \leq 0.05$	A
	7	4	100	m	4	-25.4	$p \leq 0.01$	A
					17	-31.9	$p \leq 0.01$	A
				f	17	-26.0	$p \leq 0.05$	A
Creatinine	3	1	10	m	4	+9.1	$p \leq 0.01$	A
	5	3	100	m	4	+9.8	$p \leq 0.01$	A
					17	+10.0	$p \leq 0.01$	A
	6	5	30	m	4	+7.3	$p \leq 0.01$	A

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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Creatinine *- continued*	7	4	100	m	4	+10.1	p ≤ 0.05	A
					17	+12.0	p ≤ 0.01	A
				f	17	+7.3	p ≤ 0.05	A
Glucose	2	1	30	f	17	-17.7	p ≤ 0.01	A
	3	1	10	m	4	-30.8	p ≤ 0.01	A
				f	4	-23.8	p ≤ 0.01	A
	5	3	100	m	4	-33.6	p ≤ 0.01	A
				f	17	-14.0	p ≤ 0.01	A
	6	5	30	m	4	-25.2	p ≤ 0.01	A
				f	4	-18.5	p ≤ 0.05	A
	7	4	100	m	4	-26.1	p ≤ 0.01	A
				f	4	-27.8	p ≤ 0.01	A
Phosphate	2	1	30	m	17	+18.4	p ≤ 0.01	A
				f	4	+12.7	p ≤ 0.05	A
					17	+21.7	p ≤ 0.01	A
	4	3	30	m	4	-8.8	p ≤ 0.05	A
	6	5	30	f	4	+14.9	p ≤ 0.01	A
Protein (total)	2	1	30	f	4	-5.4	p ≤ 0.05	A
	3	1	10	f	4	-9.4	p ≤ 0.01	A
					38	-11.8	p ≤ 0.01	A
	4	3	30	m	4	-5.5	p ≤ 0.01	A
					17	+6.7	p ≤ 0.01	A
	5	3	100	m	17	+10.4	p ≤ 0.01	A
	6	5	30	f	4	-6.9	p ≤ 0.01	A
	7	4	100	m	17	+7.8	p ≤ 0.01	A
Triglycerides	2	1	30	m	4	-41.0	p ≤ 0.01	A
				f	17	+39.7	p ≤ 0.05	A
	3	1	10	m	4	-70.0	p ≤ 0.01	A
				f	4	-66.6	p ≤ 0.01	A
					17	+77.4	p ≤ 0.01	A
	4	3	30	f	4	-41.9	p ≤ 0.01	A
	5	3	100	m	4	-73.5	p ≤ 0.01	A
				f	4	-65.8	p ≤ 0.01	A
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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Triglycerides *- continued*	6	5	30	m	4	-70.4	$p \leq 0.01$	A
				f	4	-56.5	$p \leq 0.01$	A
	7	4	100	m	4	-73.5	$p \leq 0.01$	A
				f	4	-71.7	$p \leq 0.01$	A
Urea (in blood)	2	1	30	m	17	+20.4	$p \leq 0.01$	A
	3	1	10	m	17	+18.6	$p \leq 0.05$	A
	5	3	100	m	17	+22.5	$p \leq 0.01$	A
	7	4	100	m	17	+35.4	$p \leq 0.01$	A
Calcium	3	1	10	m	4	-6.7	$p \leq 0.01$	A
				f	4	-4.7	$p \leq 0.01$	A
	5	3	100	m	4	-6.6	$p \leq 0.01$	A
	6	5	30	m	4	-9.1	$p \leq 0.01$	A
	7	4	100	m	4	-6.8	$p \leq 0.01$	A
Chloride	2	1	30	f	4	-1.5	$p \leq 0.01$	A
	3	1	10	m	4	+1.2	$p \leq 0.01$	A
	5	3	100	m	4	+2.1	$p \leq 0.01$	A
	6	5	30	m	4	+2.0	$p \leq 0.01$	A
	7	4	100	m	4	+2.1	$p \leq 0.01$	A
Potassium	3	1	10	m	4	-9.3	$p \leq 0.01$	A
				f	4	-9.4	$p \leq 0.05$	A
					17	+11.3	$p \leq 0.05$	A
	5	3	100	m	4	-10.7	$p \leq 0.01$	A
				f	17	+16.4	$p \leq 0.01$	A
	7	4	100	m	4	-8.0	$p \leq 0.05$	A
				f	17	+10.1	$p \leq 0.05$	A
Sodium	2	1	30	f	17	-1.3	$p \leq 0.05$	A
	3	1	10	m	4	+1.0	$p \leq 0.01$	A
					17	-1.2	$p \leq 0.05$	A
	5	3	100	m	4	+1.6	$p \leq 0.01$	A
				f	17	-1.7	$p \leq 0.01$	A
	6	5	30	m	4	+1.2	$p \leq 0.01$	A
	7	4	100	m	4	+1.6	$p \leq 0.01$	A
					17	-1.5	$p \leq 0.01$	A
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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Alanine amino-transferase (ALAT)	2	1	30	f	17	+69.0	$p \leq 0.01$	A
	3	1	10	m	4	-26.2	$p \leq 0.01$	A
				f	4	-20.6	$p \leq 0.05$	A
	5	3	100	m	4	-31.0	$p \leq 0.01$	A
				f	4	-30.0	$p \leq 0.01$	A
	6	5	30	m	4	-33.1	$p \leq 0.01$	A
	7	4	100	m	4	-32.8	$p \leq 0.01$	A
				f	4	-36.5	$p \leq 0.01$	A
Alkaline phosphatase (aP)	2	1	30	m	17	+21.2	$p \leq 0.05$	A
				f	4	+28.4	$p \leq 0.01$	A
					17	+105.4	$p \leq 0.01$	A
	3	1	10	m	4	-32.7	$p \leq 0.01$	A
				f	17	+58.8	$p \leq 0.01$	A
	4	3	30	f	17	+43.2	$p \leq 0.05$	A
	5	3	100	m	4	-27.8	$p \leq 0.01$	A
				f	17	+109.4	$p \leq 0.01$	A
	6	5	30	m	4	-29.8	$p \leq 0.01$	A
	7	4	100	m	4	-22.3	$p \leq 0.01$	A
				f	17	+142.2	$p \leq 0.01$	A
Aspartate amino-transferase (ASAT)	2	1	30	m	17	+26.8	$p \leq 0.01$	A
				f	17	+47.3	$p \leq 0.01$	A
	3	1	10	m	4	+23.9	$p \leq 0.01$	A
				f	4	+32.6	$p \leq 0.01$	A
	5	3	100	f	4	+21.7	$p \leq 0.05$	A
					17	+27.4	$p \leq 0.01$	A
	6	5	30	m	4	+18.8	$p \leq 0.01$	A
				f	4	+43.9	$p \leq 0.01$	A
	7	4	100	m	4	+19.4	$p \leq 0.01$	A
				f	4	+29.7	$p \leq 0.01$	A
					17	+24.3	$p \leq 0.05$	A
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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Lactate dehydro-genase (LDH)	5	3	100	m	4	+40.6	$p \leq 0.05$	A
				f	4	+45.2	$p \leq 0.05$	A
	6	5	30	m	4	+49.9	$p \leq 0.01$	A
				f	4	+66.0	$p \leq 0.01$	A
	7	4	100	m	4	+54.1	$p \leq 0.01$	A
				f	4	+54.8	$p \leq 0.05$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
B Change is due to the relative high or low value noted for the control group.

Group mean values of biochemical parameters are presented in Table 7-1 (Biochemical Parameters - Summary), individual data are listed in Table 7-2 (Biochemical Parameters - Individual Data).

4.9 Acute phase proteins

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period

Elevated serum levels of the acute phase proteins alpha1-acid glycoprotein and alpha2 macroglobulin were noted for all test item-treated groups in comparison to the control group on test day 4 and test day 10 or 17 as given in the text tables following on the following page.

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Text table 4-14: Test item-related changes in serum levels of alpha1-acid glycoprotein

Test item-related changes in serum levels of alpha1-acid glycoprotein compared to the control group (refer to Table 8-1), expressed as fold changes (×)								
Test day	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
4	4.7 × **	4.1 × **	7.2 × **	5.0 × **	5.9 × **	4.7 × **	7.0 × **	5.6 × **
17	14.6 × **	12.5 × **	8.5 × **	9.0 × **	8.7 × **	8.9 × **	19.3 × **	18.9 × **
Test day	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
4	6.7 × **		4.9 × **		6.9 × **		5.6 × **	
10	↑		↑					
17					20.7 × **		15.9 × **	

** Statistically significant at p ≤ 0.01 (based on the numerical data, not on the fold change).

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

Text table 4-15: Test item-related changes in serum levels of alpha2 macroglobulin

Test item-related changes in serum levels of alpha2 macroglobulin compared to the control group (refer to Table 8-1), expressed as fold changes (×)								
Test day	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
4	5.6 ×	3.2 × **	18.3 × **	7.0 × **	36.1 × **	18.3 × **	53.9 × **	90.6 × **
17	18.6 × **	6.4 × **	26.0 × **	16.8 × **	43.8 × **	45.1 × **	279.2 × **	167.7 × **
Test day	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
4	17.2 × **		9.4 × **		54.3 × **		75.3 × **	
10	↑		↑					
17					216.9 × **		120.7 × **	

** Statistically significant at p ≤ 0.01 (based on the numerical data, not on the fold change)

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

All changes noted for the acute phase proteins are considered to be related to the primary pharmacodynamic activity of the intramuscularly delivered vaccines, which induce a local pro-inflammatory environment within the injected muscle and thereby promote a potent immune response.

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Recovery period

The elevated serum levels of alpha1-acid glycoprotein and alpha2 macroglobulin noted during the treatment period had subsided in all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups). The serum levels of both acute phase proteins were in a range comparable to that of the control group in all previously test item-treated groups.

Statistically significant differences in serum levels of acute phase proteins in comparison to the control group noted during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental are listed in the text table below.

Text table 4-16: Statistically significant differences in serum levels of acute phase proteins considered not test item-related

Statistically significant differences in serum levels of acute phase proteins in comparison to the control group considered not test item-related (refer to Table 8-1)								
Acute phase proteins	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Alpha1-acid glycoprotein	3	1	10	m	38	-48.9	$p \leq 0.01$	A
	5	3	100	m	38	-42.7	$p \leq 0.01$	A
				f	38	-53.2	$p \leq 0.05$	A
	7	4	100	m	38	-47.8	$p \leq 0.01$	A
Alpha2 macroglobulin	5	3	100	m	38	+52.9	$p \leq 0.05$	A
	7	4	100	m	38	+63.7	$p \leq 0.05$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7

m male
f female

A Change is due to the relative high or low value noted for the control group.

Mean values per group and individual data of acute phase proteins are listed in Table 8-1 (Acute Phase Protein Levels - Summary) and Table 8-2 (Acute Phase Protein Levels - Individual Data).

The mean acute phase protein levels per group and sex are shown graphically in Figure 5-1 (Alpha1-acid glycoprotein, males), Figure 5-2 (Alpha1-acid glycoprotein, females), Figure 6-1 (Alpha2 macroglobulin, males), and Figure 6-2 (Alpha2 macroglobulin, females) on the following pages.

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Figure 5-1 Alpha1-acid glycoprotein levels in serum of male rats mean values per group and standard deviation

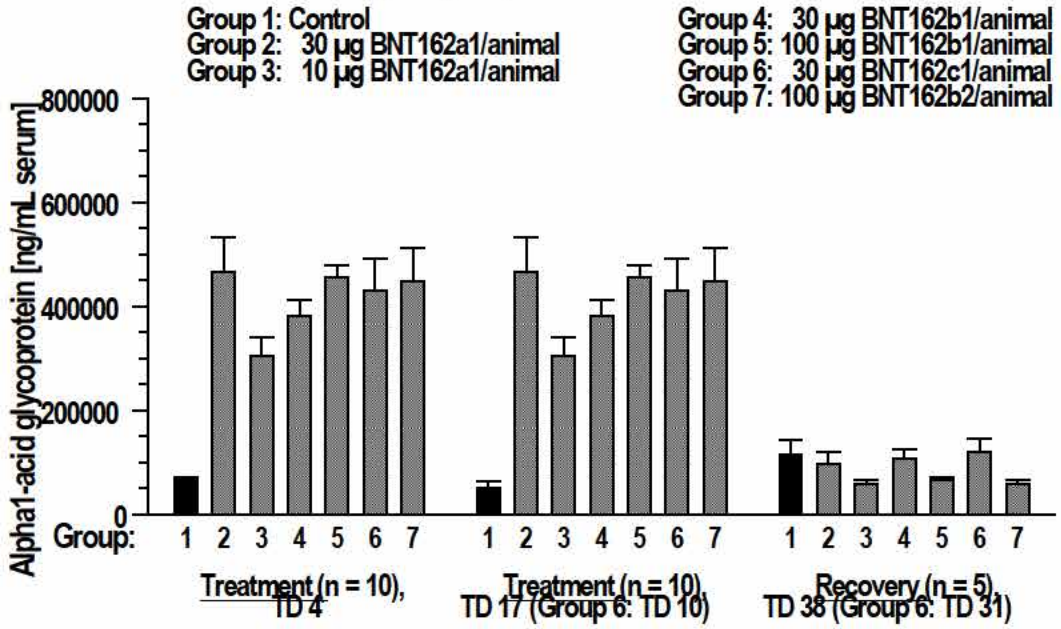

Figure 5-2 Alpha1-acid glycoprotein levels in serum of female rats mean values per group and standard deviation

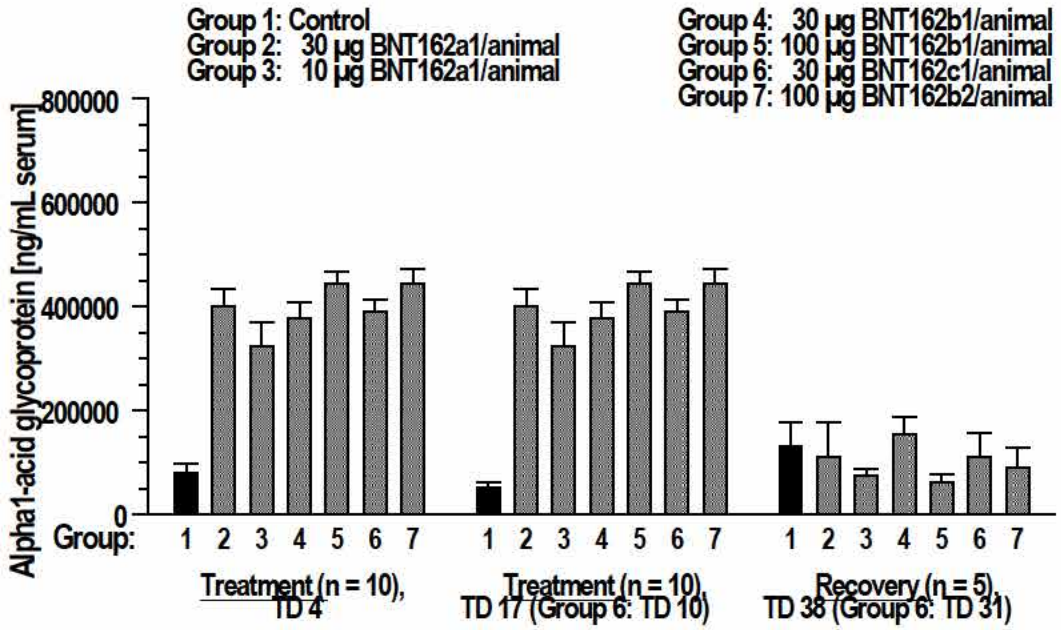

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Figure 6-1 Alpha2 macroglobulin levels in serum of male rats mean values per group and standard deviation

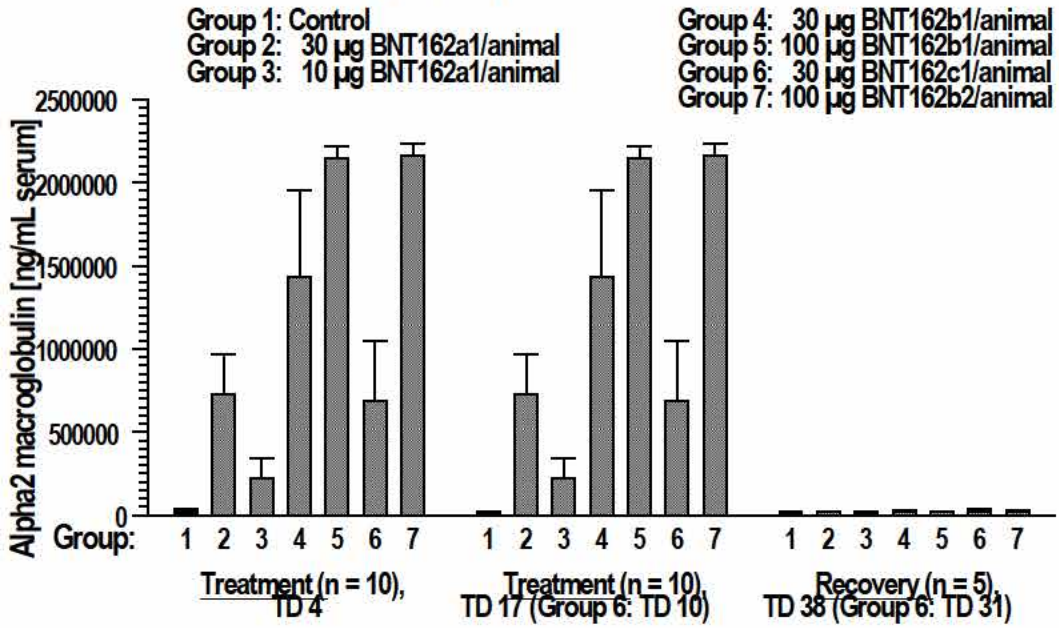
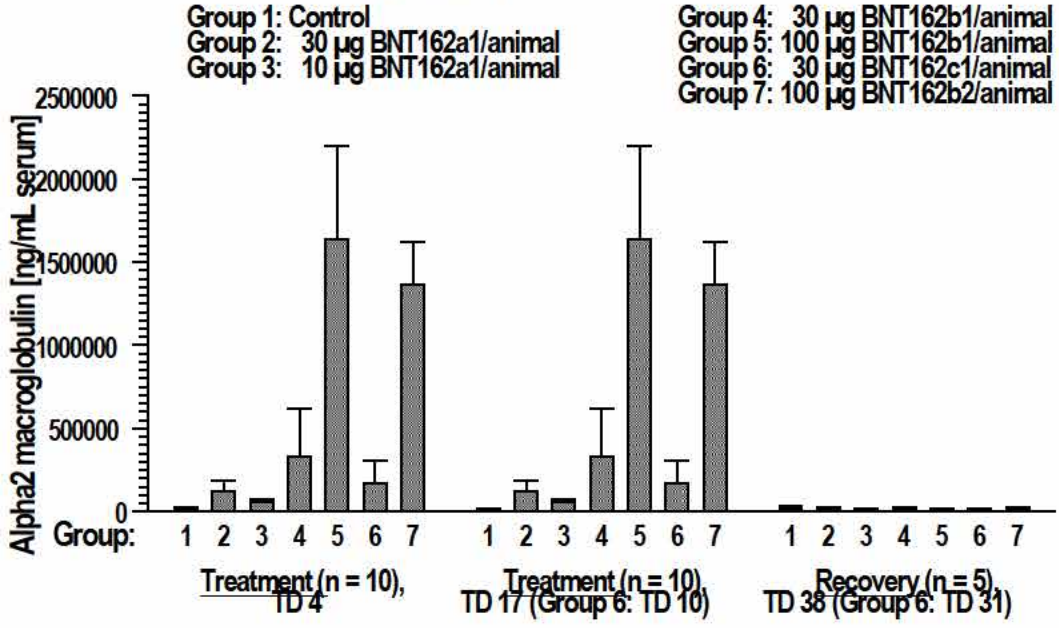


Figure 6-2 Alpha2 macroglobulin levels in serum of female rats mean values per group and standard deviation



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4.10 Cytokines

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery

Elevated serum levels of the cytokines IFN-gamma, TNF-alpha, IL-1beta, IL-6, and IL-10 were noted in all study groups, including the control, compared to the respective predose value as of 6 h p.a. on test day 1. There were no general differences between the test item-treated groups and the control group and among the various test item-treated groups.

A large variability of data was observed using only 3 or 5 animals per group and sex. Therefore, all data obtained are considered to be within the normal range of biological variation. Any differences between the test item-treated animals and the control group are considered as coincidental changes.

Statistically significant differences in cytokine serum levels in comparison to the control group during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental changes are listed in the text table below.

Text table 4-17: Statistically significant differences in cytokine serum levels considered not test item-related

Statistically significant differences in cytokine serum levels in comparison to the control group considered not test item-related (refer to Table 9-1)								
Cytokine	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day (time point)**	**Change [%]**	**Statistical significance**	**Reason**
IFN-gamma	2	1	30	m	15 (6 h p.a.)	+52.2	$p \leq 0.05$	B
					17 (48 h p.a.)	+2679.2	$p \leq 0.05$	B, C
				f	17 (48 h p.a.)	+342.0	$p \leq 0.05$	B, C
	6	5	30	f	8 (6 h p.a.)	+111.2	$p \leq 0.01$	B
TNF-alpha	3	1	10	m	8 (Predose)	-91.1	$p \leq 0.05$	B

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Statistically significant differences in cytokine serum levels in comparison to the control group considered not test item-related (refer to Table 9-1)								
Cytokine	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day (time point)**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
IL-1beta	2	1	30	m	1 (Predose)	+131.7	$p \leq 0.05$	A
	3	1	10	m	8 (Predose)	-96.7	$p \leq 0.05$	B, C
	7	4	100	m	8 (Predose)	-88.6	$p \leq 0.05$	B, C
IL-6	3	1	10	m	1 (6 h p.a.)	-75.7	$p \leq 0.05$	B, D
					15 (6 h p.a.)	+417.0	$p \leq 0.01$	B, C
	5	3	100	m	15 (6 h p.a.)	+468.9	$p \leq 0.01$	B, C
				f	15 (6 h p.a.)	+481.6	$p \leq 0.05$	B, C
	6	5	30	m	1 (6 h p.a.)	-75.7	$p \leq 0.05$	B, D

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change observed predose to start of administration.
B Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
C Change is due to the relative high or low value noted for the control group.
D Change due to mean at level of LLOQ (all individual data are equal to LLOQ).

Mean values per group and individual data of cytokine levels are listed in Table 9-1 (Cytokine Levels - Summary) and Table 9-2 (Cytokine Levels - Individual Data).

The mean cytokine levels per group and sex are shown graphically in Figure 7-1 (IFN-gamma, males), Figure 7-2 (IFN-gamma, females), Figure 8-1 (TNF-alpha, males), Figure 8-2 (TNF-alpha, females), Figure 9-1 (IL-1beta, males), Figure 9-2 (IL-1beta, females), Figure 10-1 (IL-6, males), Figure 10-2 (IL-6, females), Figure 11-1 (IL-10, males), and Figure 11-2 (IL-10, females) on the following pages.

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Figure 7-1 IFN-gamma levels in serum of male rats mean values per group and standard deviation

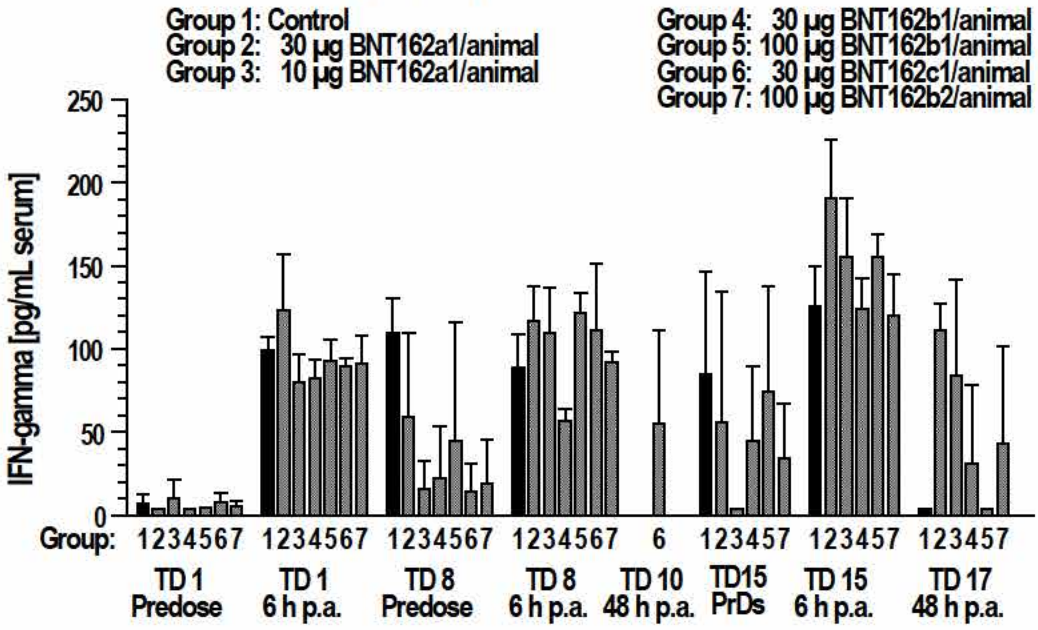

Figure 7-2 IFN-gamma levels in serum of female rats mean values per group and standard deviation

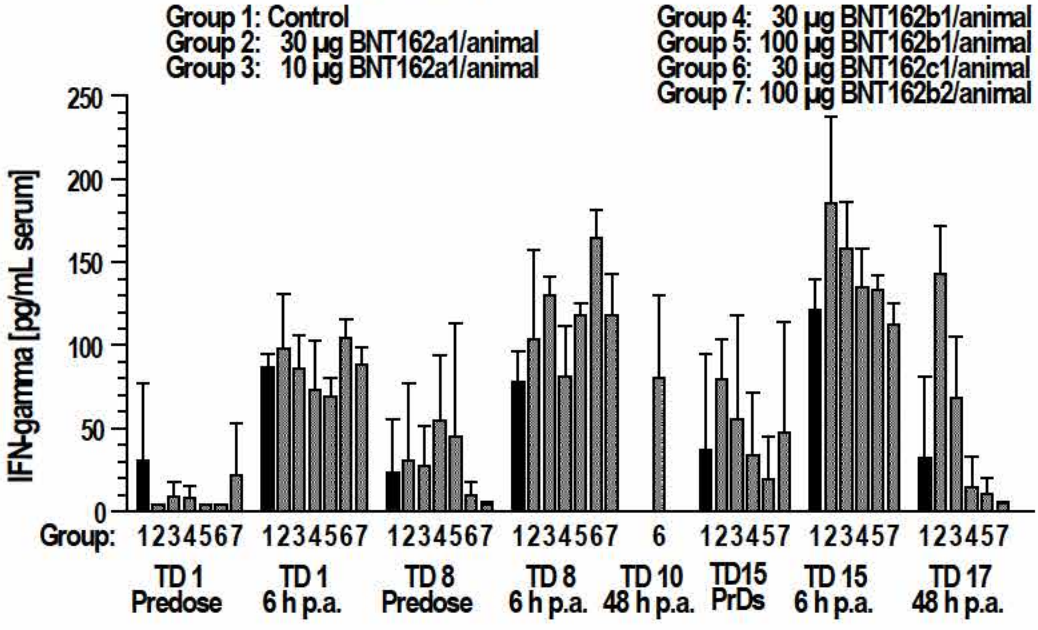

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Figure 8-1 TNF-alpha levels in serum of male rats mean values per group and standard deviation

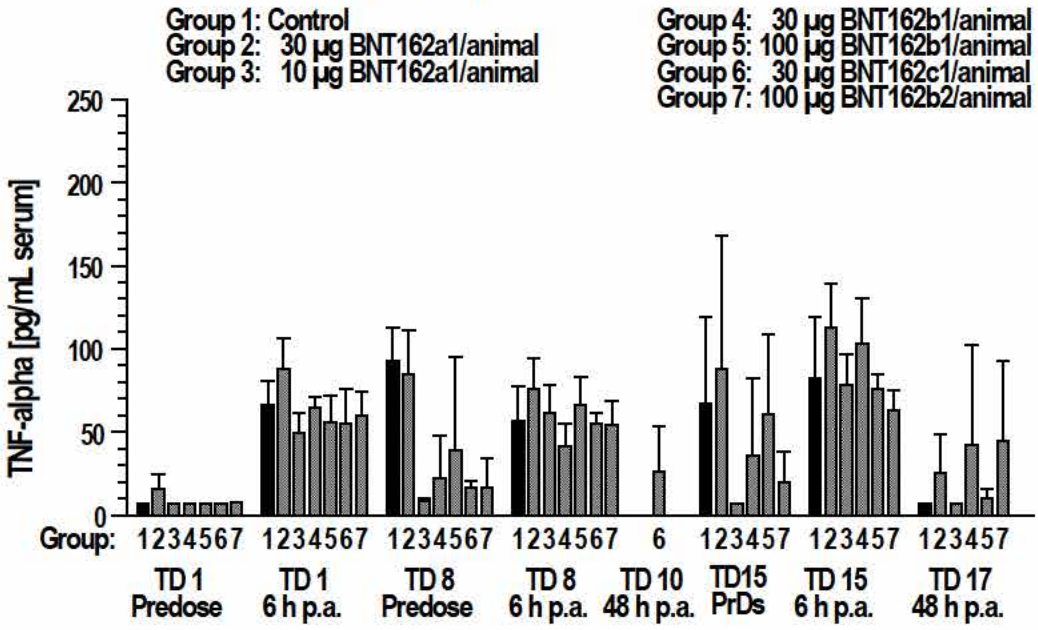
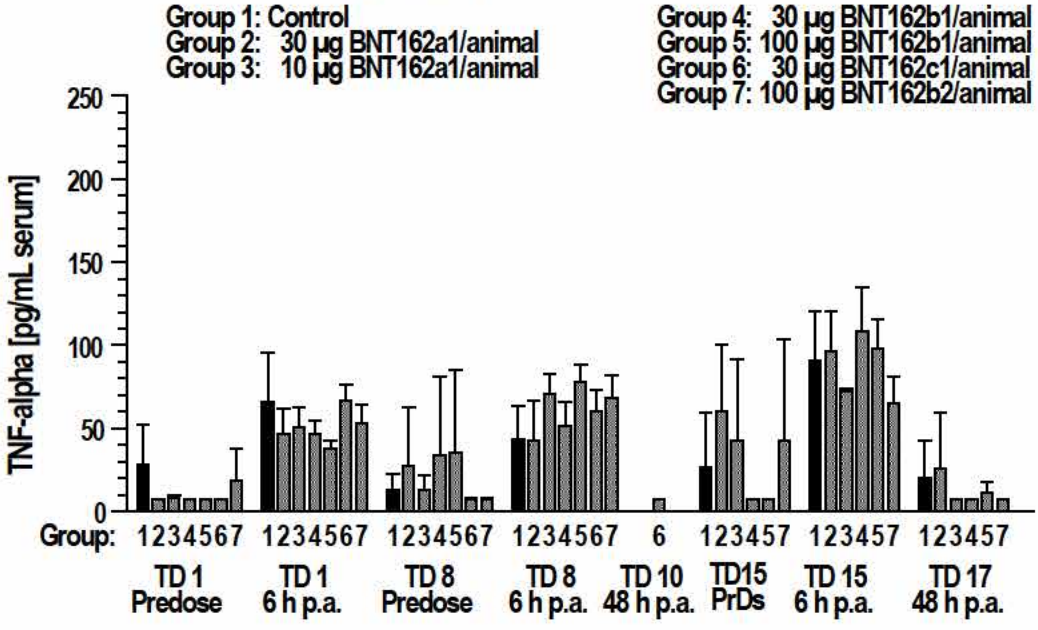


Figure 8-2 TNF-alpha levels in serum of female rats mean values per group and standard deviation



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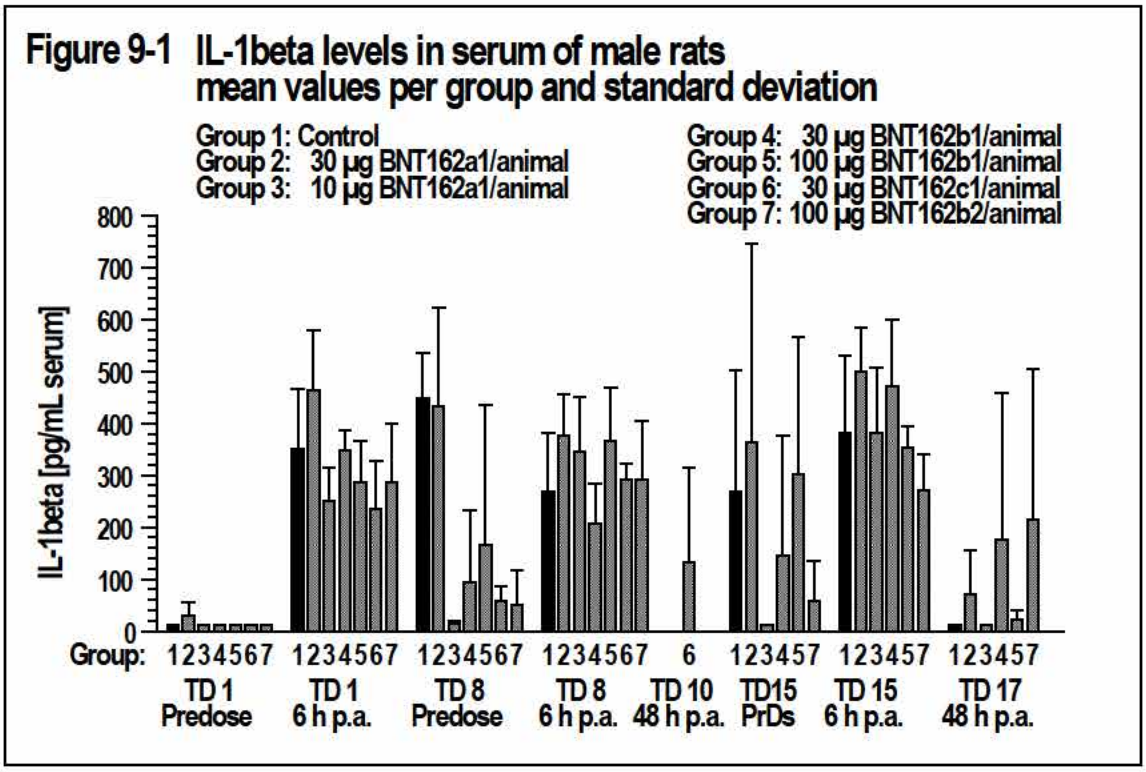

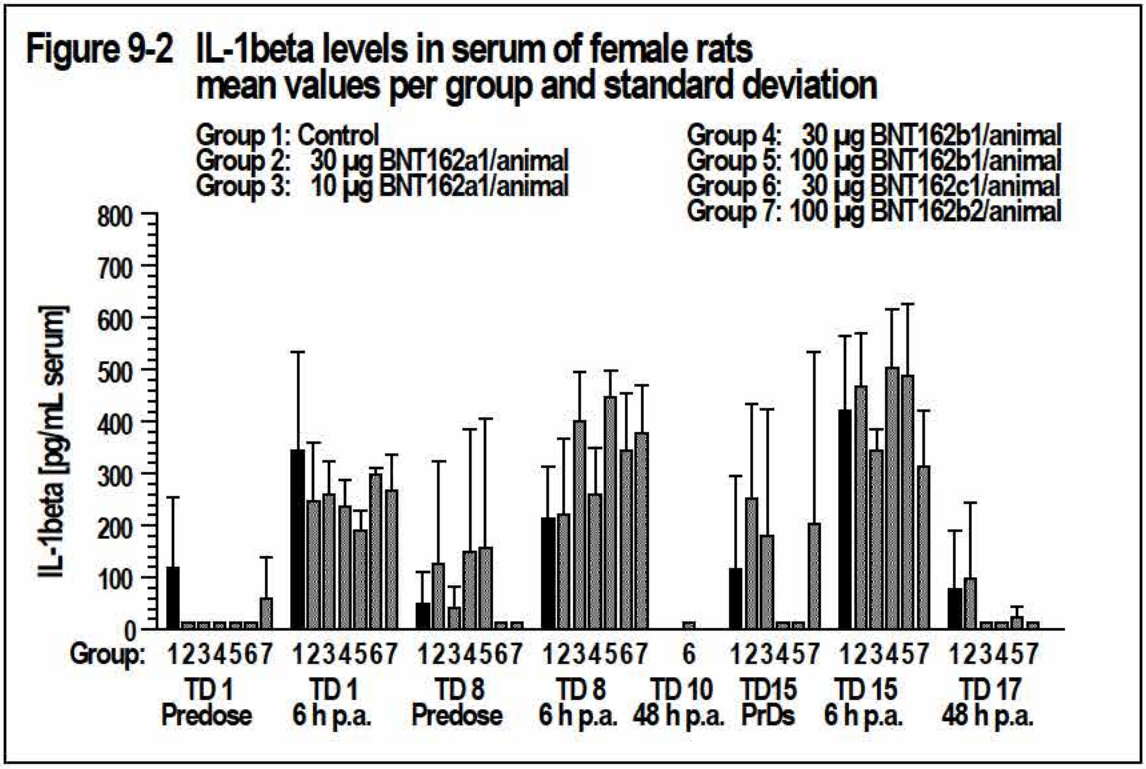

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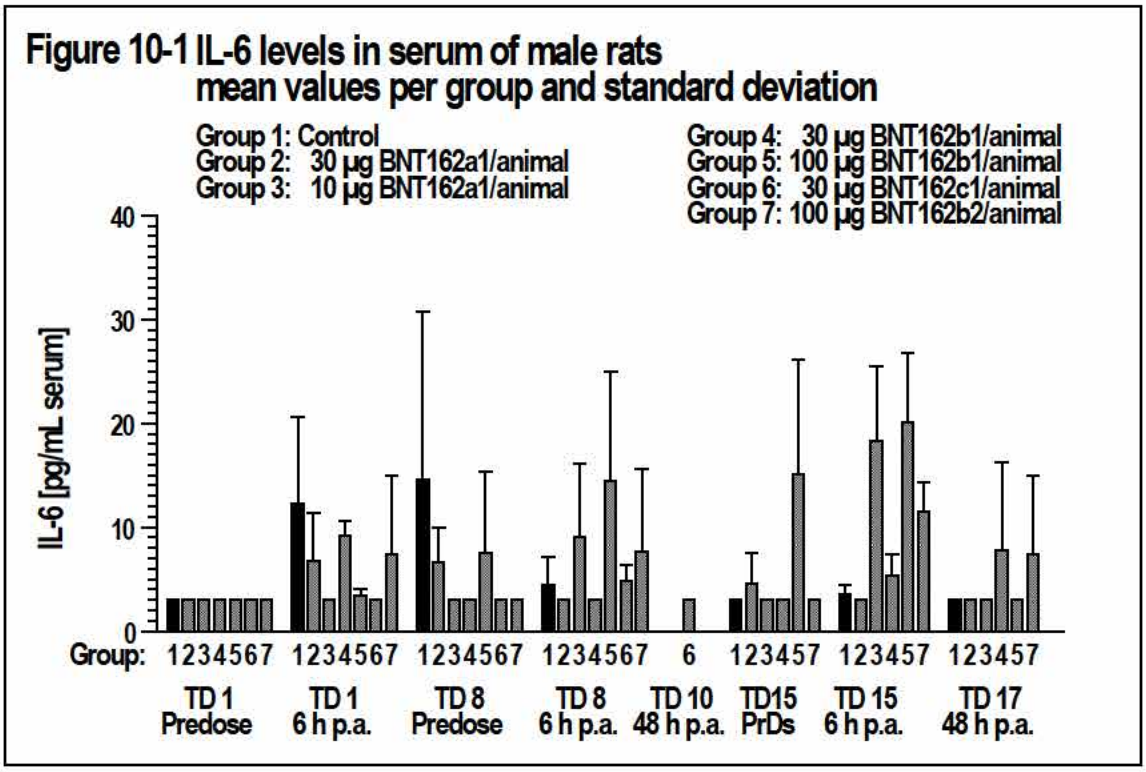

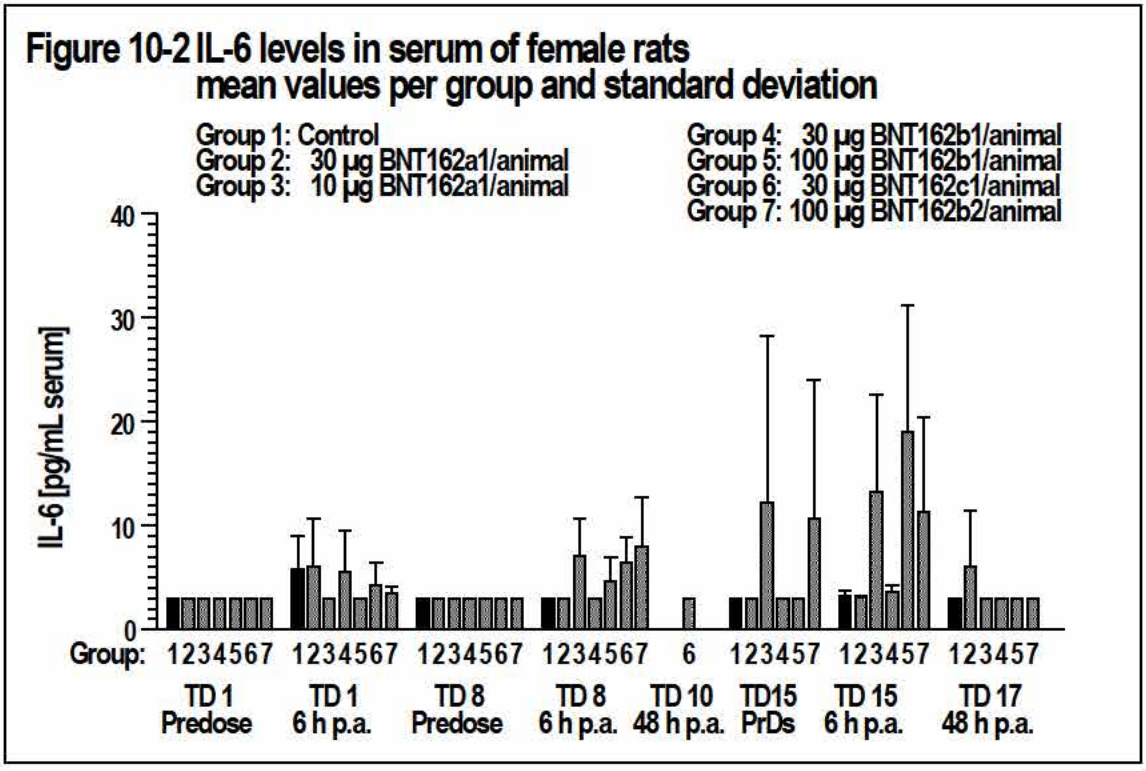

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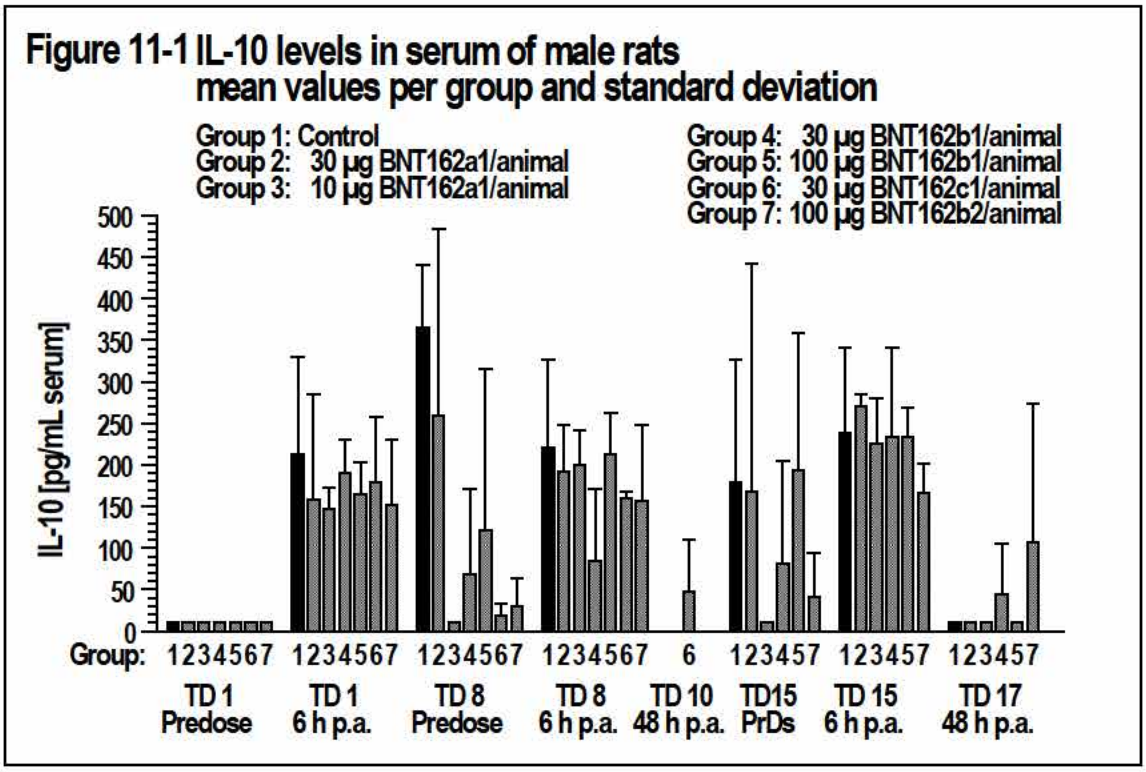

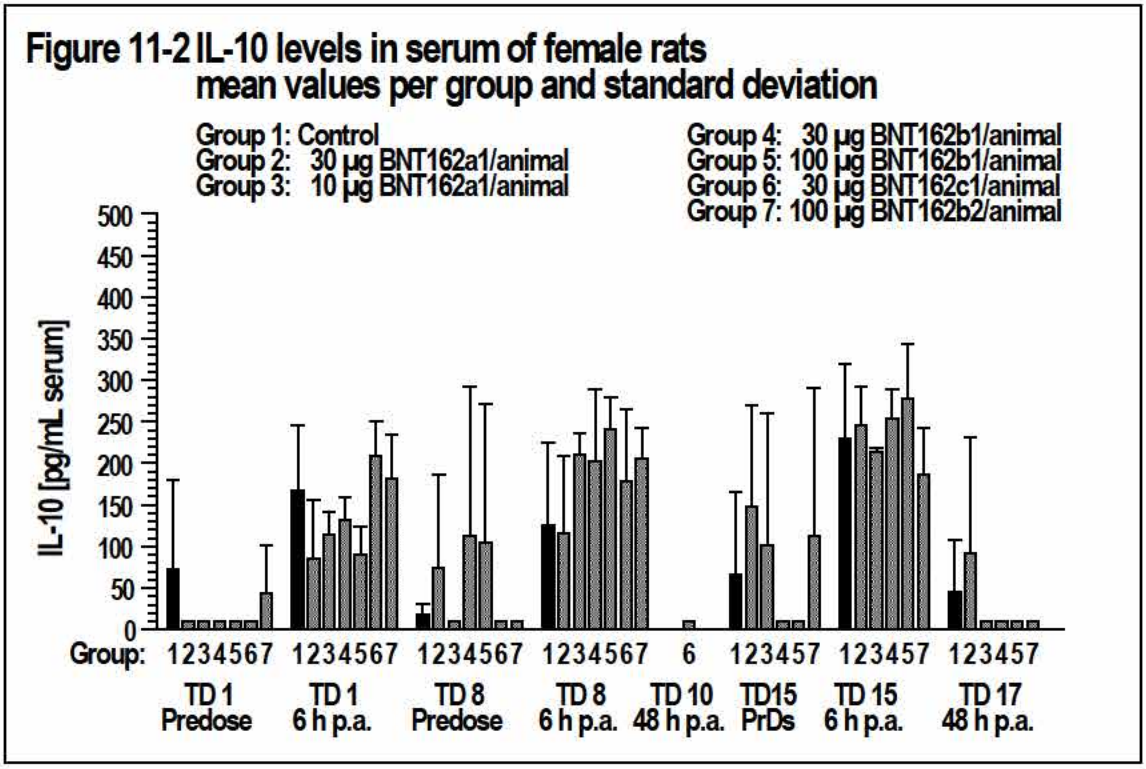

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4.11 Urinalysis

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery period

Intramuscular treatment with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8 did not lead to any test item-related changes of the urinary parameters in the male and female animals compared to the respective control animals.

No test item-related changes were noted for the specific gravity, the pH value of the urine and the urine volume. The analyte concentrations of nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and haemoglobin were not influenced in a test item-related way in male and female animals. No test item-related changes were observed in the urine colour and the microscopically analysed urine sediments.

Text table 4-18: Statistically significant changes in urinary parameters considered not test item-related

Statistically significant changes in urinary parameters (refer to Table 10-1) in comparison to the control group considered not test item-related								
Urinary parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Specific gravity	4	3	30	m	17	+1.3	$p \leq 0.01$	A
				f	17	+2.0	$p \leq 0.01$	A
	5	3	100	m	17	+1.4	$p \leq 0.01$	A
	7	4	100	m	17	+1.5	$p \leq 0.01$	A
Urine volume	4	3	30	m	17	-32.7	$p \leq 0.01$	B
	5	3	100	m	17	-26.2	$p \leq 0.05$	B
	7	4	100	m	17	-30.9	$p \leq 0.01$	B

Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7

m male
f female

A Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
B Change is due to the relative high or low value noted for the control group.

Group mean values of urinary parameters are presented in Table 10-1 (Urinalysis - Summary), individual data are listed in Table 10-2 (Urinalysis - Individual Data).

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4.12 Immunogenicity assessment

The serum samples prepared from the blood collected at terminal dissection and recovery dissection (see Section 3.8.8) were analysed by BioNTech SE, Germany, under the responsibility of the Sponsor. A summary from the analytical report forwarded to **LPT** is given following below.

'*The recorded data demonstrates that all BNT162 vaccine candidates elicited a SARS-CoV-2-S protein specific antibody response directed against the S1 domain and the RBD sub-domain. The antibody response induced by the BNT162c1 vaccine was low in extent and did not confer neutralization activity in most animals. The development of the BNT162c1 candidate was discontinued. For BNT162a1, BNT162b1 and BNT162b2 vaccines, antibody responses detected via ELISA increased over time and directly translated into neutralizing activity as seen in the VSV/SARS-CoV-2-S pseudovirus neutralization test. For those vaccine candidates, sera from animals with higher antigen-specific antibody titers also displayed more pronounced virus neutralization effect and, in case of modRNA based vaccines, BNT162b1 and BNT162b2, exceeded the upper limit of quantification of the assay.*'

For details, refer to the analytical report 'Immunogenicity Assessment of BNT162a1, BNT162b1, BNT162b2 and BNT162c1 in Rat Serum after Repeated Intramuscular Administration' provided by BioNTech SE, Germany, in Appendix 4.

4.13 Ophthalmological and auditory examinations

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery period

The ophthalmological examination did not reveal any changes of the eyes and the optic region for the male and female animals following intramuscular treatment with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8 at the end of the treatment period and at the end of the recvorey period.

There was no indication of any impairment to the auditory acuity through any treatment.

See Table 11 (Ophthalmological Examination) and Table 12 (Auditory Examination) for listings of individual findings.

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4.14 Macroscopic *post mortem* findings

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Terminal sacrifice

Test item-related findings were noted for all test items and all dose levels in male and female animals as given in the text tables following below.

Text table 4-19: Incidences of test item-related macroscopic findings for the animals treated with BNT162a1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17 (refer to Table 13)				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation: - Injection site I and/or II thickened / indurated / (skin) incrusted	3/10	1/10	5/10	5/10
Injection site I (left): - Muscle(s) indurated / muscles thickened / indurated	7/10	8/10	10/10	10/10
Spleen: - Enlarged	5/10	2/10	2/10	4/10
Lymph node (iliac): - Enlarged	4/10	3/10	1/10	1/10

.../... Number of animals affected per number of animals examined.

Text table 4-20: Incidences of test item-related macroscopic findings for the animals treated with BNT162b1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17 (refer to Table 13)				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation: - Injection site I and/or II thickened	0/10	0/10	1/10	1/10
Injection site I and/or II (left/right): - Muscle(s) indurated / muscles thickened / indurated / enlarged	7/10	6/10	7/10	6/10
Spleen: - Enlarged	1/10	1/10	5/10	7/10
Lymph node (iliac or renal, left): - Enlarged	6/10	4/10	7/10	8/10

.../... Number of animals affected per number of animals examined.

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Text table 4-21: Incidences of test item-related macroscopic findings for the animals treated with BNT162c1 or BNT162b2

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 10 (group 6) or test day 17 (group 7) (refer to Table 13)				
Organ / Finding	**Group 6: 30 µg BNT162c1/animal**		**Group 7: 100 µg BNT162b2/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened and/or incrusted	9/10	9/10	1/10	1/10
Injection site I and/or II (left/right):				
- Muscle(s) indurated or jellied / thickened / indurated / enlarged	10/10	10/10	7/10	9/10
Spleen:				
- Enlarged	5/10	1/10	2/10	7/10
Lymph node (iliac or iliac/renal):				
- Enlarged	1/10	2/10	5/10	6/10
Sciatic nerve (left):				
- Adhered to injection site I	0/10	0/10	0/10	3/10

.../... Number of animals affected per number of animals examined.

All systemic changes noted macroscopically are interpreted to be due to inflammation at the injection site and/or immune activation.

Recovery sacrifice

All macroscopic findings noted at the injection sites and for the spleen had subsided in all animals of all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups)

Enlarged iliac lymph nodes were still noted for a few animals as follows:

Group 4 (30 µg BNT162b1/animal): One of 5 females.
Group 5 (100 µg BNT162b1/animal): All 5 males, 2 of 5 females.
Group 7 (100 µg BNT162b2/animal): One of 5 males, 3 of 5 females.

These findings are regarded to be related to the previous test item treatment.

Further findings in form of emphysematous lungs, a reddened thymus, an enlarged right testis, a dilated uterus, in some cases filled with a clear liquid, a prostate and seminal vesicles that were reduced in size, and enlarged adrenal glands were noted for individual male and female animals in the test item-treated groups and the control group at terminal sacrifice or at recovery sacrifice. Due to the isolated occurrence per finding, all of these findings are considered as spontaneous changes that are not test item-related.

The macroscopic findings of individual animals are listed in Table 13 (Macroscopic Post Mortem Findings).

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4.15 Organ weights

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Main study animals

In accordance with the macroscopic findings of enlarged spleens (see Section 4.11), increased relative and absolute spleen weights were noted for all test items at all dose levels in male and female animals as given in the text table following below.

Text table 4-22: Test item-related changes in spleen weights

Test item-related changes in spleen weights compared to the control group in % (test day 10/group 6, test day 17/groups 2 to 5 and 7, refer to Table 14-1 and Table 15-1)								
Organ weight	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
Rel.	+27.8**	+25.7	+39.6**	+67.4**	+22.3**	+23.8	+30.0**	+49.4**
Abs.	+28.8**	+23.4	+16.5	+58.2**	+13.5	+30.6*	+22.9**	+54.8**
Organ weight	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
Rel.	↑		↑		+36.6**		+62.3**	
Abs.	↑		↑		+25.2**		+60.8**	

Rel. relative (to body weight)
Abs. absolute
*/** Statistically significant at $p \leq 0.05$ / $p \leq 0.01$ (based on numerical data, not on percent difference).
↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

All other differences between any of the test item-treated groups 2 to 7 and the control group at the end of the treatment period (test day 10 for group 6, test day 17 for groups 2 to 5 and 7), or at the end of the recovery period (test day 31 for group 6, test day 38 for groups 2 to 5 and 7) are considered to be coincidental background changes within the normal range of biological variation.

Recovery period

The slightly increased spleen weights noted at the end of the treatment period for the male and female animals of all dose groups had subsided at the end of the recovery period. There were no noteworthy differences in the absolute and relative weights of any organ between the test item-treated animals and the control animals at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups).

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Statistically significant differences in organ weights compared to the control animals that are not considered to be test item-related are listed in the text table below.

Text table 4-23: Statistically significant organ weight changes considered not test item-related

Statistically significant differences in organ weights (refer to Table 14-1 and Table 15-1) in comparison to the control group considered not test item-related									
Organ		**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Adrenal gland (left)	- rel.	2	1	30	m	17	+31.0	p ≤ 0.01	A, D
						38	+23.0	p ≤ 0.05	A
		7	4	100	m	17	+23.4	p ≤ 0.05	A, D
	- abs.	2	1	30	m	38	+18.3	p ≤ 0.05	A
					f	38	-19.3	p ≤ 0.01	A, B
		3	1	10	f	38	-26.0	p ≤ 0.01	A, B
		4	3	30	f	38	-19.6	p ≤ 0.05	A, B
Adrenal gland (right)	- rel.	2	1	30	m	17	+38.6	p ≤ 0.01	A, D
					f	38	-21.8	p ≤ 0.05	A
		3	1	10	f	38	-23.9	p ≤ 0.05	A
		4	3	30	f	38	-24.3	p ≤ 0.05	A
		5	3	100	m	17	+28.0	p ≤ 0.05	A, D
	- abs.	2	1	30	f	38	-23.5	p ≤ 0.01	A, B
		3	1	10	f	38	-27.0	p ≤ 0.01	A, B
		4	3	30	f	38	-25.6	p ≤ 0.01	A, B
Brain	- rel.	2	1	30	m	17	+17.2	p ≤ 0.01	A, D
Epididymis (left)	- rel.	3	1	10	m	17	+25.5	p ≤ 0.01	A, D
		5	3	100	m	17	+23.6	p ≤ 0.05	A, D
		7	4	100	m	17	+32.5	p ≤ 0.05	A, D
	- abs.	3	1	10	m	17	+26.3	p ≤ 0.01	A, C
		7	4	100	m	17	+21.2	p ≤ 0.05	A, C
Epididymis (right)	- rel.	2	1	30	m	17	+26.2	p ≤ 0.01	A, B, D
		3	1	10	m	17	+24.2	p ≤ 0.01	A, B, D
		4	3	30	m	17	+18.7	p ≤ 0.05	A, B, D
		5	3	100	m	17	+36.5	p ≤ 0.01	A, B, D
		7	4	100	m	17	+33.9	p ≤ 0.01	A, B, D
	- abs.	3	1	10	m	17	+25.1	p ≤ 0.01	A, B, D
						38	+22.1	p ≤ 0.05	A, C
		5	3	100	m	17	+28.6	p ≤ 0.01	A, C
						38	+17.2	p ≤ 0.05	A, C
		7	4	100	m	17	+22.7	p ≤ 0.05	A, C

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Statistically significant differences in organ weights (refer to Table 14-1 and Table 15-1) in comparison to the control group considered not test item-related									
Organ		Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -									
Testis (left)	- rel.	2	1	30	m	17	+16.5	p ≤ 0.01	A, D
		7	4	100	m	17	+12.1	p ≤ 0.01	A
Testis (right	- rel.	2	1	30	m	17	+18.8	p ≤ 0.01	A, D
		7	4	100	m	17	+11.8	p ≤ 0.01	A
Heart	- rel.	2	1	30	m	17	+15.2	p ≤ 0.01	A, D
		7	4	100	m	17	+8.8	p ≤ 0.05	A
Kidney (left)	- rel.	2	1	30	m	17	+10.3	p ≤ 0.05	A, D
					f	17	+11.9	p ≤ 0.01	A, D
		5	3	100	m	17	+10.1	p ≤ 0.05	A, D
		7	4	100	f	17	+8.9	p ≤ 0.05	A, D
Kidney (right)	- rel.	2	1	30	f	17	+9.1	p ≤ 0.01	A, D
		7	4	100	f	17	+8.0	p ≤ 0.01	A, D
Liver	- rel.	2	1	30	f	17	+15.7	p ≤ 0.01	A, D
		3	1	10	f	38	-10.9	p ≤ 0.05	A
		4	3	30	f	17	+10.3	p ≤ 0.05	A
		5	3	100	f	17	+15.3	p ≤ 0.01	A, D
		7	4	100	f	17	+20.6	p ≤ 0.01	A, D
	- abs.	2	1	30	m	17	-18.7	p ≤ 0.01	A, D
		4	3	30	m	17	-10.0	p ≤ 0.01	A, D
					f	17	+15.8	p ≤ 0.01	A
		5	3	100	f	17	+20.6	p ≤ 0.01	A, C
		7	4	100	f	17	+19.2	p ≤ 0.01	A, C
Lungs	- rel.	2	1	30	m	17	+14.5	p ≤ 0.01	A, D
					f	17	+18.0	p ≤ 0.01	A, D
		3	1	10	f	17	+13.8	p ≤ 0.05	A, D
		7	4	100	f	17	+15.2	p ≤ 0.05	A, D
Lymph node (mesent.)	- rel.	5	3	100	m	38	+86.3	p ≤ 0.05	A, C
	- abs.	3	1	10	m	38	+74.6	p ≤ 0.05	A, C
		5	3	100	m	38	+85.7	p ≤ 0.05	A, C
Thyroid/Par. (left)	- rel.	2	1	30	m	17	+26.5	p ≤ 0.05	A, D
		4	3	30	f	17	-30.5	p ≤ 0.05	A, E
		5	3	100	f	17	-29.9	p ≤ 0.05	A, E
- Text table continued on the next page -									

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Statistically significant differences in organ weights (refer to Table 14-1 and Table 15-1) in comparison to the control group considered not test item-related									
Organ		**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -									
Thymus	- rel.	7	4	100	m	17	-21.3	$p \leq 0.05$	A, D
	- abs.	7	4	100	m	17	-27.9	$p \leq 0.01$	A

m male
f female

rel. relative
abs. absolute

A Change is within normal range of biological variation, without toxicological relevance.
B Change is due to the relatively low or high value noted for the control group.
C Change is related to the older age of the animals.
D Change is due to the slightly lower body weights of the respective test item treated animals compared to the control animals.
E Change is due to the slightly higher body weights of the respective test item treated animals compared to the control animals.

Relative organ weights are listed in Table 14-1 (Relative Organ Weights - Summary) and Table 14-2 (Relative Organ Weights - Individual Data). Absolute organ weights are listed in Table 15-1 (Absolute Organ Weights - Summary) and Table 15-2 (Absolute Organ Weights - Individual Data).

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4.16 Histopathology

Terminal sacrifice

Test item-related microscopic findings at the end of dosing included inflammation at the injection site and surrounding tissues, increased cellularity of germinal centers and increased plasma cells in the draining (iliac) lymph node, increased cellularity (hematopoiesis) in the bone marrow and spleen, and vacuolation of hepatocytes in the portal regions. All microscopic findings were partially or fully recovered at the end of the 3 week recovery phase.

Test item-related injection site reactions were present in all groups and characterized by mostly moderate inflammation (up to marked) in males and moderate inflammation in females. The most severe findings were noted consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate oedema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. Injection site findings were partially recovered at the end of the 3-week recovery phase. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac). These findings were mostly recovered at the end of the 3-week recovery phase.

Test item-related findings in the draining (iliac) lymph node were characterized by increased cellularity of the follicular germinal centers and increased plasma cells (plasmacytosis) and were variably present in all groups.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen were present in all groups.

A test item-related vacuolation of hepatocytes in the portal regions of the liver was present in all groups.

Test item-related findings were noted for all test items and all dose levels in male and female animals as given in the text tables following on the next pages.

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Text table 4-24: Incidences of test item-related microscopic findings for the animals treated with BNT162a1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site l (left):				
- Fibrosis intramuscular/interstitial	10/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	10/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	9/10**	9/10**	9/10**
- Oedema, subcutis	10/10**	9/10**	6/10*	10/10**
- Oedema intramuscular/interstitial	7/10**	8/10**	2/10	10/10**
- Oedema inter-/ perimuscular	10/10**	10/10**	7/10**	10/10**
- Hyperplasia, epidermis	9/10**	7/10**	10/10**	9/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	1/10	3/10	0/10
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	1/10	0/10	1/10
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	3/10	0/10	0/10
Lymph node (iliac):				
- Plasmacytosis	7/10**	7/10**	5/10*	3/10
- Inflammation	0/10	3/10	5/10*	6/10*
- Increased cellularity, germinal center	9/10	10/10**	9/10	8/10
Spleen:				
- Increased haematopoiesis	3/10	2/10	0/10	0/10
Liver				
- Vacuolation, hepatocellular, periportal	1/10	6/10*	1/10	10/10**

.../... number of animals affected per number of animals examined

* significantly different from control ($p \leq 0.05$)

** significantly different from control ($p \leq 0.01$)

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Text table 4-25: Incidences of test item-related microscopic findings for the animals treated with BNT162b1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	10/10**	10/10**	10/10**
- Oedema, subcutis	9/10**	10/10**	10/10**	10/10**
- Oedema intramuscular/interstitial	8/10**	9/10**	10/10**	10/10**
- Oedema inter-/ perimuscular	10/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	8/10**	10/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	1/10	4/10	7/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	4/10	6/10*
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	0/10	2/10	1/10
Lymph node (iliac):				
- Plasmacytosis	9/10**	8/10**	8/10**	10/10**
- Inflammation	0/10	0/10	5/10*	8/9**
- Increased cellularity, geminal center	10/10	8/10	10/10	10/10**
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	7/10**
Liver				
- Vacuolation, hepatocellular, periportal	0/10	10/10**	8/10**	10/10**

.../... number of animals affected per number of animals examined

* significantly different from control ($p \leq 0.05$)

** significantly different from control ($p \leq 0.01$)

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Text table 4-26: Incidences of test item-related microscopic findings for the animals treated with BNT162c1 and BNT162b2

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 10 (group 6) or test day 17 (group 7)				
Organ / Finding	**BNT162c1**		**BNT162b2**	
	Group 6: 30 µg/animal		**Group 7: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed	9/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	8/10**	9/10**	10/10**	10/10**
- Oedema, subcutis	9/10**	10/10**	10/10**	10/10**
- Oedema intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Oedema inter-/ perimuscular	9/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	10/10**	9/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	0/10	10/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	2/10	9/10**
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	4/10	2/10	0/10
Lymph node (iliac):				
- Plasmacytosis	6/10*	7/10**	10/10**	10/10**
- Inflammation	4/10	7/10**	9/10**	6/10*
- Increased cellularity, germinal center	10/10	10/10**	10/10	10/10**
Skeletal muscle:				
- Infiltration, lymphohistiogranulocyt.	0/10	0/10	5/10*	0/10
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	8/10**
Liver				
- Vacuolation, hepatocellular, periportal	1/10	10/10**	9/10**	10/10**

.../... number of animals affected per number of animals examined

* significantly different from control ($p \leq 0.05$)

** significantly different from control ($p \leq 0.01$)

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Recovery sacrifice

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland; skeletal muscle) and spleen were partially or completely recovered in all animals at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups). Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals, being less severe (minimal to mild) if not resolved; plasmacytosis in the iliac lymph node was less severe and present in fewer groups (30 or 100 µg BNT162b1/animal or 100 µg BNT162b2/animal) at the end of the 3-week recovery period, indicating partial or complete recovery.

The infiltration of macrophages in the iliac lymph nodes of previously treated recovery animals were regarded as consequence of phagocytosis relating to the inflammatory reactions at the injection sites.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen was fully recovered at the end of the 3-week recovery phase.

Test item-related vacuolation of hepatocytes in the portal regions of the liver was fully recovered at the end of the 3-week recovery phase.

The incidence and the severity of the remaining findings were markedly reduced compared to the main study animals.

The complete Histopathology Report is given in Section 6.

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5. TABLES

Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 1: Control (2 × 100 µl Buffer/animal)

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
1	n/a	n/a	No signs of local intolerance
2	n/a	n/a	No signs of local intolerance
3	n/a	n/a	No signs of local intolerance
4	n/a	n/a	No signs of local intolerance
5	n/a	n/a	No signs of local intolerance
6	n/a	n/a	No signs of local intolerance
7	n/a	n/a	No signs of local intolerance
8	n/a	n/a	No signs of local intolerance
9	n/a	n/a	No signs of local intolerance
10	n/a	n/a	No signs of local intolerance

- *Group 1 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 1: Control (2 × 100 µl Buffer/animal)- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
11	n/a	n/a	No signs of local intolerance
12	n/a	n/a	No signs of local intolerance
13	n/a	n/a	No signs of local intolerance
14	n/a	n/a	No signs of local intolerance
15	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
11	n/a	n/a	No signs of local intolerance
12	n/a	n/a	No signs of local intolerance
13	n/a	n/a	No signs of local intolerance
14	n/a	n/a	No signs of local intolerance
15	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 2: 30 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
31	n/a	n/a	No signs of local intolerance
32	14	1	Eschar formation (injection site)
33	n/a	n/a	No signs of local intolerance
34	14	1	Eschar formation (injection site)
35	n/a	n/a	No signs of local intolerance
36	n/a	n/a	No signs of local intolerance
37	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
38	n/a	n/a	No signs of local intolerance
39	14	1	Eschar formation (injection site)
40	n/a	n/a	No signs of local intolerance

- *Group 2 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 2: 30 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
41	n/a	n/a	No signs of local intolerance
42	14	1	Eschar formation (injection site)
43	9, 10	2	Injection site appears to be painful
44	9	1	Injection site appears to be painful
45	9	1	Injection site appears to be painful

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
41	n/a	n/a	No signs of local intolerance
42	n/a	n/a	No signs of local intolerance
43	n/a	n/a	No signs of local intolerance
44	n/a	n/a	No signs of local intolerance
45	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 3: 10 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
61	n/a	n/a	No signs of local intolerance
62	n/a	n/a	No signs of local intolerance
63	n/a	n/a	No signs of local intolerance
64	n/a	n/a	No signs of local intolerance
65	n/a	n/a	No signs of local intolerance
66	n/a	n/a	No signs of local intolerance
67	n/a	n/a	No signs of local intolerance
68	n/a	n/a	No signs of local intolerance
69	n/a	n/a	No signs of local intolerance
70	n/a	n/a	No signs of local intolerance

- *Group 3 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 3: 10 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
71	n/a	n/a	No signs of local intolerance
72	n/a	n/a	No signs of local intolerance
73	n/a	n/a	No signs of local intolerance
74	n/a	n/a	No signs of local intolerance
75	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
71	n/a	n/a	No signs of local intolerance
72	n/a	n/a	No signs of local intolerance
73	n/a	n/a	No signs of local intolerance
74	n/a	n/a	No signs of local intolerance
75	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 4: 30 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
91	n/a	n/a	No signs of local intolerance
92	n/a	n/a	No signs of local intolerance
93	n/a	n/a	No signs of local intolerance
94	n/a	n/a	No signs of local intolerance
95	n/a	n/a	No signs of local intolerance
96	n/a	n/a	No signs of local intolerance
97	n/a	n/a	No signs of local intolerance
98	n/a	n/a	No signs of local intolerance
99	n/a	n/a	No signs of local intolerance
100	n/a	n/a	No signs of local intolerance

- *Group 4 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 4: 30 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
101	n/a	n/a	No signs of local intolerance
102	n/a	n/a	No signs of local intolerance
103	n/a	n/a	No signs of local intolerance
104	n/a	n/a	No signs of local intolerance
105	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
101	n/a	n/a	No signs of local intolerance
102	n/a	n/a	No signs of local intolerance
103	n/a	n/a	No signs of local intolerance
104	n/a	n/a	No signs of local intolerance
105	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 5: 100 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
121	n/a	n/a	No signs of local intolerance
122	n/a	n/a	No signs of local intolerance
123	n/a	n/a	No signs of local intolerance
124	n/a	n/a	No signs of local intolerance
125	n/a	n/a	No signs of local intolerance
126	n/a	n/a	No signs of local intolerance
127	n/a	n/a	No signs of local intolerance
128	n/a	n/a	No signs of local intolerance
129	n/a	n/a	No signs of local intolerance
130	n/a	n/a	No signs of local intolerance

- *Group 5 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 5: 100 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
131	n/a	n/a	No signs of local intolerance
132	n/a	n/a	No signs of local intolerance
133	n/a	n/a	No signs of local intolerance
134	n/a	n/a	No signs of local intolerance
135	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
131	n/a	n/a	No signs of local intolerance
132	n/a	n/a	No signs of local intolerance
133	n/a	n/a	No signs of local intolerance
134	n/a	n/a	No signs of local intolerance
135	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 6: 30 µg BNT162c1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
151	n/a	n/a	No signs of local intolerance
152	n/a	n/a	No signs of local intolerance
153	n/a	n/a	No signs of local intolerance
154	n/a	n/a	No signs of local intolerance
155	n/a	n/a	No signs of local intolerance
156	n/a	n/a	No signs of local intolerance
157	n/a	n/a	No signs of local intolerance
158	n/a	n/a	No signs of local intolerance
159	n/a	n/a	No signs of local intolerance
160	n/a	n/a	No signs of local intolerance

- *Group 6 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 6: 30 µg BNT162c1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
161	n/a	n/a	No signs of local intolerance
162	n/a	n/a	No signs of local intolerance
163	n/a	n/a	No signs of local intolerance
164	n/a	n/a	No signs of local intolerance
165	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
161	n/a	n/a	No signs of local intolerance
162	n/a	n/a	No signs of local intolerance
163	n/a	n/a	No signs of local intolerance
164	n/a	n/a	No signs of local intolerance
165	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 7: 100 µg BNT162b2/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
181	n/a	n/a	No signs of local intolerance
182	n/a	n/a	No signs of local intolerance
183	n/a	n/a	No signs of local intolerance
184	n/a	n/a	No signs of local intolerance
185	n/a	n/a	No signs of local intolerance
186	n/a	n/a	No signs of local intolerance
187	n/a	n/a	No signs of local intolerance
188	n/a	n/a	No signs of local intolerance
189	n/a	n/a	No signs of local intolerance
190	n/a	n/a	No signs of local intolerance

- *Group 7 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 7: 100 µg BNT162b2/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
191	n/a	n/a	No signs of local intolerance
192	n/a	n/a	No signs of local intolerance
193	n/a	n/a	No signs of local intolerance
194	n/a	n/a	No signs of local intolerance
195	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
191	n/a	n/a	No signs of local intolerance
192	n/a	n/a	No signs of local intolerance
193	n/a	n/a	No signs of local intolerance
194	n/a	n/a	No signs of local intolerance
195	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 1: Control (2 × 100 µl Buffer/animal)

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
16	n/a	n/a	No signs of local intolerance
17	n/a	n/a	No signs of local intolerance
18	n/a	n/a	No signs of local intolerance
19	n/a	n/a	No signs of local intolerance
20	n/a	n/a	No signs of local intolerance
21	n/a	n/a	No signs of local intolerance
22	n/a	n/a	No signs of local intolerance
23	n/a	n/a	No signs of local intolerance
24	n/a	n/a	No signs of local intolerance
25	n/a	n/a	No signs of local intolerance

- *Group 1 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 1: Control (2 × 100 µl Buffer/animal)- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
26	n/a	n/a	No signs of local intolerance
27	n/a	n/a	No signs of local intolerance
28	n/a	n/a	No signs of local intolerance
29	n/a	n/a	No signs of local intolerance
30	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
26	n/a	n/a	No signs of local intolerance
27	n/a	n/a	No signs of local intolerance
28	n/a	n/a	No signs of local intolerance
29	n/a	n/a	No signs of local intolerance
30	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 2: 30 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
46	14	1	Eschar formation (injection site)
47	n/a	n/a	No signs of local intolerance
48	n/a	n/a	No signs of local intolerance
49	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
50	9	1	Injection site appears to be painful
51	9	1	Injection site appears to be painful
52	9	1	Injection site appears to be painful
53	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
54	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
55	9	1	Injection site appears to be painful

- *Group 2 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 2: 30 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
56	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
57	9	1	Injection site appears to be painful
58	9	1	Injection site appears to be painful
59	9	1	Injection site appears to be painful
60	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
56	n/a	n/a	No signs of local intolerance
57	n/a	n/a	No signs of local intolerance
58	n/a	n/a	No signs of local intolerance
59	n/a	n/a	No signs of local intolerance
60	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 3: 10 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
76	n/a	n/a	No signs of local intolerance
77	n/a	n/a	No signs of local intolerance
78	n/a	n/a	No signs of local intolerance
79	n/a	n/a	No signs of local intolerance
80	n/a	n/a	No signs of local intolerance
81	n/a	n/a	No signs of local intolerance
82	n/a	n/a	No signs of local intolerance
83	n/a	n/a	No signs of local intolerance
84	n/a	n/a	No signs of local intolerance
85	n/a	n/a	No signs of local intolerance

- *Group 3 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 3: 10 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
86	n/a	n/a	No signs of local intolerance
87	n/a	n/a	No signs of local intolerance
88	n/a	n/a	No signs of local intolerance
89	n/a	n/a	No signs of local intolerance
90	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
86	n/a	n/a	No signs of local intolerance
87	n/a	n/a	No signs of local intolerance
88	n/a	n/a	No signs of local intolerance
89	n/a	n/a	No signs of local intolerance
90	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 4: 30 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
106	n/a	n/a	No signs of local intolerance
107	n/a	n/a	No signs of local intolerance
108	n/a	n/a	No signs of local intolerance
109	n/a	n/a	No signs of local intolerance
110	n/a	n/a	No signs of local intolerance
111	n/a	n/a	No signs of local intolerance
112	n/a	n/a	No signs of local intolerance
113	n/a	n/a	No signs of local intolerance
114	n/a	n/a	No signs of local intolerance
115	n/a	n/a	No signs of local intolerance

- *Group 4 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 4: 30 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
116	n/a	n/a	No signs of local intolerance
117	n/a	n/a	No signs of local intolerance
118	n/a	n/a	No signs of local intolerance
119	n/a	n/a	No signs of local intolerance
120	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
116	n/a	n/a	No signs of local intolerance
117	n/a	n/a	No signs of local intolerance
118	n/a	n/a	No signs of local intolerance
119	n/a	n/a	No signs of local intolerance
120	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 5: 100 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
136	n/a	n/a	No signs of local intolerance
137	n/a	n/a	No signs of local intolerance
138	n/a	n/a	No signs of local intolerance
139	n/a	n/a	No signs of local intolerance
140	n/a	n/a	No signs of local intolerance
141	n/a	n/a	No signs of local intolerance
142	n/a	n/a	No signs of local intolerance
143	n/a	n/a	No signs of local intolerance
144	n/a	n/a	No signs of local intolerance
145	n/a	n/a	No signs of local intolerance

- *Group 5 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 5: 100 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
146	n/a	n/a	No signs of local intolerance
147	n/a	n/a	No signs of local intolerance
148	n/a	n/a	No signs of local intolerance
149	n/a	n/a	No signs of local intolerance
150	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
146	n/a	n/a	No signs of local intolerance
147	n/a	n/a	No signs of local intolerance
148	n/a	n/a	No signs of local intolerance
149	n/a	n/a	No signs of local intolerance
150	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 6: 30 µg BNT162c1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
166	n/a	n/a	No signs of local intolerance
167	n/a	n/a	No signs of local intolerance
168	n/a	n/a	No signs of local intolerance
169	n/a	n/a	No signs of local intolerance
170	n/a	n/a	No signs of local intolerance
171	n/a	n/a	No signs of local intolerance
172	n/a	n/a	No signs of local intolerance
173	n/a	n/a	No signs of local intolerance
174	n/a	n/a	No signs of local intolerance
175	n/a	n/a	No signs of local intolerance

- *Group 6 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 6: 30 µg BNT162c1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
176	n/a	n/a	No signs of local intolerance
177	n/a	n/a	No signs of local intolerance
178	n/a	n/a	No signs of local intolerance
179	n/a	n/a	No signs of local intolerance
180	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
176	n/a	n/a	No signs of local intolerance
177	n/a	n/a	No signs of local intolerance
178	n/a	n/a	No signs of local intolerance
179	n/a	n/a	No signs of local intolerance
180	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 7: 100 µg BNT162b2/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
196	n/a	n/a	No signs of local intolerance
197	n/a	n/a	No signs of local intolerance
198	n/a	n/a	No signs of local intolerance
199	n/a	n/a	No signs of local intolerance
200	n/a	n/a	No signs of local intolerance
201	n/a	n/a	No signs of local intolerance
202	n/a	n/a	No signs of local intolerance
203	n/a	n/a	No signs of local intolerance
204	n/a	n/a	No signs of local intolerance
205	n/a	n/a	No signs of local intolerance

- *Group 7 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 7: 100 µg BNT162b2/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
206	n/a	n/a	No signs of local intolerance
207	n/a	n/a	No signs of local intolerance
208	n/a	n/a	No signs of local intolerance
209	n/a	n/a	No signs of local intolerance
210	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
206	n/a	n/a	No signs of local intolerance
207	n/a	n/a	No signs of local intolerance
208	n/a	n/a	No signs of local intolerance
209	n/a	n/a	No signs of local intolerance
210	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Males (1) E	Oe	I/H	F	(2) E	Oe	I/H	F	(3) E	Oe	I/H	F	(4) E	Oe	I/H	F	(5) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Males (6) E	Oe	I/H	F	(7) E	Oe	I/H	F	(8) E	Oe	I/H	F	(9) E	Oe	I/H	F	(10) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Males (11) E	Oe	I/H	F	(12) E	Oe	I/H	F	(13) E	Oe	I/H	F	(14) E	Oe	I/H	F	(15) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	3/2	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
Recovery period																					
17 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Females (16) E	Oe	I/H	F	(17) E	Oe	I/H	F	(18) E	Oe	I/H	F	(19) E	Oe	I/H	F	(20) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Females (21) E	Oe	I/H	F	(22) E	Oe	I/H	F	(23) E	Oe	I/H	F	(24) E	Oe	I/H	F	(25) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Females (26) E	Oe	I/H	F	(27) E	Oe	I/H	F	(28) E	Oe	I/H	F	(29) E	Oe	I/H	F	(30) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	3/2	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
Recovery period																					
17 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (31) E	Oe	I/H	F	(32) E	Oe	I/H	F	(33) E	Oe	I/H	F	(34) E	Oe	I/H	F	(35) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	2	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	2	0	-
5 (96 h)		0	0	0	S	1	0	0	S	0	0	0	S	0	0	0	S	1	1	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1	0	-	1	2	0	-	1	2	0	-	0	2	0	-
10 (48 h)		0	0	0	-	2	1	0	-	1	2	0	-	2	2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	1	0	0	-	1	1	0	-	1	1	0	-	0	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (36) E	Oe	I/H	F	(37) E	Oe	I/H	F	(38) E	Oe	I/H	F	(39) E	Oe	I/H	F	(40) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	2	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-
5 (96 h)		0	0	0	S	1	0	0	S	0	1	0	S	1	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	0	3	0	-	1	2	0	-	0	1	0	-	0	2	0	-
10 (48 h)		1	2	0	-	1	3	0	-	0	1	0	-	1	1	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (41) E	Oe	I/H	F	(42) E	Oe	I/H	F	(43) E	Oe	I/H	F	(44) E	Oe	I/H	F	(45) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	0	0	-	0	0	0	-
5 (96 h)		1	0	0	S	1	1	0	S	1	0	0	S	0	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	1	0	-	0	2	0	-	1	3	0	-	0	3	0	-	0	3	0	-
10 (48 h)		0	3	0	-	1	2	0	-	1	3	0	-	0	3/2	0	-	1	2	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	1	2	0	-	0	1	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	1	0	-	0	0	0	-	1	2	0	-	0	2	0	-	1	2	0	-
19 (96 h)		4	0	0	-	4	0	0	-	4	2	0	-	4	1	0	-	4	2	0	-
21 (144 h)		1	0	0	-	1	0	0	-	1	1	0	-	0	0	0	-	0	0	0	-
23 (192 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
27 (288 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		1	0	0	T	1	0	0	T	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		1	0	0	T	1	0	0	T	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		1	0	0	T	1	0	0	T	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin
T: Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (46) E	Oe	I/H	F	(47) E	Oe	I/H	F	(48) E	Oe	I/H	F	(49) E	Oe	I/H	F	(50) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
5 (96 h)		0	0	0	S	1	0	0	S	1	0	0	S	0	0	0	S	0	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	3	0	-
10 (48 h)		0	2	0	-	1	0	0	-	1	2	0	-	1	3	0	-	0	2	0	-
12 (96 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
		S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (51) E	Oe	I/H	F	(52) E	Oe	I/H	F	(53) E	Oe	I/H	F	(54) E	Oe	I/H	F	(55) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		1	1	0	S	1	1	0	S	1	0	0	S	0	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	1	2	0	-	0	2	0	-	1	3	0	-	1	2	0	-
10 (48 h)		1	2	0	-	1	3	0	-	1	3	0	-	1	3	0	-	1	3	0	-
12 (96 h)		0	0	0	-	0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	1	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (56) E	Oe	I/H	F	(57) E	Oe	I/H	F	(58) E	Oe	I/H	F	(59) E	Oe	I/H	F	(60) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	2	0	-	0	0	0	-	0	2	0	-	0	2	0	-	0	1	0	-
5 (96 h)		0	0	0	S	0	0	0	S	0	1	0	S	0	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
10 (48 h)		1	2	0	-	0	2	0	-	0	3	0	-	0	3/2	0	-	2	2	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-	1	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	1	0	-	0	1	0	-	0	1	0	-	1	2	0	-
Recovery period																					
17 (48 h)		1	2	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-
19 (96 h)		4	2	0	-	4	2	0	-	4	2	0	-	4	1	0	-	4	0/1	0	-
21 (144 h)		1	0	0	-	0	0	0	-	2	0	0	-	2	0	0	-	2	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	1	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	4	1	0	-	4	0	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	4	1	0	-	4	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	2	0	0	-	2	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	T	0	0	0	T	0	0	0	T
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	T

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin
		T:	Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (61) E	Oe	I/H	F	(62) E	Oe	I/H	F	(63) E	Oe	I/H	F	(64) E	Oe	I/H	F	(65) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	3	0	-	0	3	0	-	0	2	0	-	0	3	0	-
12 (96 h)		0	2	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (66) E	Oe	I/H	F	(67) E	Oe	I/H	F	(68) E	Oe	I/H	F	(69) E	Oe	I/H	F	(70) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	2	0	-	0	2	0	-	0	3	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	4	1	0	-	0	0	0	-	4	0	2	-	0	1	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	1	1	0	-	0	2	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (71) E	Oe	I/H	F	(72) E	Oe	I/H	F	(73) E	Oe	I/H	F	(74) E	Oe	I/H	F	(75) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	1	0	-
Recovery period																					
17 (48 h)		1	0	0	-	1	0	1	-	1	1	0	-	0	2	0	-	0	2	0	-
19 (96 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	2	0	-	0	0	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	2	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	3	-	0	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (76) E	Oe	I/H	F	(77) E	Oe	I/H	F	(78) E	Oe	I/H	F	(79) E	Oe	I/H	F	(80) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	0	0	-	0	1	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	4	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	1	2	0	-	0	2	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (81) E	Oe	I/H	F	(82) E	Oe	I/H	F	(83) E	Oe	I/H	F	(84) E	Oe	I/H	F	(85) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	3	0	-	0	3	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (86) E	Oe	I/H	F	(87) E	Oe	I/H	F	(88) E	Oe	I/H	F	(89) E	Oe	I/H	F	(90) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-
Recovery period																					
17 (48 h)		1	1	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (91) E	Oe	I/H	F	(92) E	Oe	I/H	F	(93) E	Oe	I/H	F	(94) E	Oe	I/H	F	(95) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	2	0	-	0	1	0	-	0	2	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
		S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (96) E	Oe	I/H	F	(97) E	Oe	I/H	F	(98) E	Oe	I/H	F	(99) E	Oe	I/H	F	(100) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	2	0	-	0	1	0	-	0	1	0	-	1	0	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	1	1	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (101) E	Oe	I/H	F	(102) E	Oe	I/H	F	(103) E	Oe	I/H	F	(104) E	Oe	I/H	F	(105) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	S	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	1	2	0	-	1	1	0	-	0	1	0	-
10 (48 h)		0	0	0	-	0	0	0	-	1	1	0	-	0	3/2	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	1	0	-	0	2	0	-	1	2	0	-	0	1	0	-	0	2	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
27 (288 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	2	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	1	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	1	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin
T: Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (106) E	Oe	I/H	F	(107) E	Oe	I/H	F	(108) E	Oe	I/H	F	(109) E	Oe	I/H	F	(110) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	2	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	0	0	-
5 (96 h)		0	0	0	S	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	1	2	0	-	0	1	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (111) E	Oe	I/H	F	(112) E	Oe	I/H	F	(113) E	Oe	I/H	F	(114) E	Oe	I/H	F	(115) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	S	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	1	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (116) E	Oe	I/H	F	(117) E	Oe	I/H	F	(118) E	Oe	I/H	F	(119) E	Oe	I/H	F	(120) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	2	0	-	0	0	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-	0	2	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	1	3/2	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-
Recovery period																					
17 (48 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
27 (288 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin
T: Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (121) E	Oe	I/H	F	(122) E	Oe	I/H	F	(123) E	Oe	I/H	F	(124) E	Oe	I/H	F	(125) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0/1	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1/0	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	2/3	0	-	0	2	0	-	0	2	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (126) E	Oe	I/H	F	(127) E	Oe	I/H	F	(128) E	Oe	I/H	F	(129) E	Oe	I/H	F	(130) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1/0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1/0	0	-	0	0	0	-	0	1	0	-	0	1/0	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	3	0	-	0	3/2	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2/3	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (131) E	Oe	I/H	F	(132) E	Oe	I/H	F	(133) E	Oe	I/H	F	(134) E	Oe	I/H	F	(135) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1/0	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	2	0	-	0	3/2	0	-	0	3	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	2/3	0	-	0	2	0	-	0	3	0	-	0	3/2	0	-	0	3	0	-
19 (96 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1/2	0	-
27 (288 h)		0	1	0	-	0	0	0	-	0	0/1	0	-	0	1	0	-	0	1	0	-
29 (336 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	1/0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (136) E	Oe	I/H	F	(137) E	Oe	I/H	F	(138) E	Oe	I/H	F	(139) E	Oe	I/H	F	(140) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		1	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0/1	0/1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	2/3	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (141) E	Oe	I/H	F	(142) E	Oe	I/H	F	(143) E	Oe	I/H	F	(144) E	Oe	I/H	F	(145) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	0	0	-	1/0	1/0	0	-	0	0	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	1/0	0	-	0	1/0	0	-	0	1	0	-
10 (48 h)		0	3	0	-	0	3/2	0	-	0	3	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2/3	0	-	1/0	2	0	-	0	3	0	-	0	2	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (146) E	Oe	I/H	F	(147) E	Oe	I/H	F	(148) E	Oe	I/H	F	(149) E	Oe	I/H	F	(150) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-
3 (48 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	3/2	0	-	0	3/2	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	2	0	-
19 (96 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1/2	0	-	0	1	0	-	0	1	0	-	0	1/0	0	-	0	1	0	-
27 (288 h)		0	0/1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (151) E	Oe	I/H	F	(152) E	Oe	I/H	F	(153) E	Oe	I/H	F	(154) E	Oe	I/H	F	(155) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (156) E	Oe	I/H	F	(157) E	Oe	I/H	F	(158) E	Oe	I/H	F	(159) E	Oe	I/H	F	(160) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (161) E	Oe	I/H	F	(162) E	Oe	I/H	F	(163) E	Oe	I/H	F	(164) E	Oe	I/H	F	(165) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-
5 (96 h)		0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
Recovery period																					
10 (48 h)		0	3	0	-	0	4	0	-	0	4	0	-	0	3	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	4	0	0	-	4	0	0	-	4	0	0	-	4	0	0	-
16 (192 h)		0	0	0	-	0	2	0	-	0	0	0	-	0	0	0	-	0	0	0	-
18 (240 h)		0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
20 (288 h)		0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
22 (336 h)		0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
24 (384 h)		0	0	0	-	4	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-
26 (432 h)		0	0	0	-	1	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-
28 (480 h)		0	0	0	-	1	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-
30 (528 h)		0	0	0	-	1	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	C:	Incrusted wound / Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (166) E	Oe	I/H	F	(167) E	Oe	I/H	F	(168) E	Oe	I/H	F	(169) E	Oe	I/H	F	(170) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (171) E	Oe	I/H	F	(172) E	Oe	I/H	F	(173) E	Oe	I/H	F	(174) E	Oe	I/H	F	(175) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	2	0	-
5 (96 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	1	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (176) E	Oe	I/H	F	(177) E	Oe	I/H	F	(178) E	Oe	I/H	F	(179) E	Oe	I/H	F	(180) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	1	0	0	-	1	1	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
Recovery period																					
10 (48 h)		0	3	0	-	0	2	0	-	0	3	0	-	0	3	0	-	0	3	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-
16 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
18 (240 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
20 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
22 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
24 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
26 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
28 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
30 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Males (181) E	Oe	I/H	F	(182) E	Oe	I/H	F	(183) E	Oe	I/H	F	(184) E	Oe	I/H	F	(185) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0/1	0	-	0	0/1	0	-	0	1	0	-	0	0/1	0	-
3 (48 h)		0	1	0	-	0	0/1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	3	0	-	0	3/2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	2	0	-	0	3	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Males (186) E	Oe	I/H	F	(187) E	Oe	I/H	F	(188) E	Oe	I/H	F	(189) E	Oe	I/H	F	(190) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1/0	0	-	0	1/0	0	-	0	1/0	0	-	0	1/0	0	-
3 (48 h)		0	0/1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1/0	0	-	0	1/0	0	-	0	1/0	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	3/2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	4	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	3	0	-	0	3	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Males (191) E	Oe	I/H	F	(192) E	Oe	I/H	F	(193) E	Oe	I/H	F	(194) E	Oe	I/H	F	(195) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	0/1	0	-	0	1/0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	1	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	3/2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	3/4	0	-	0	3	0	-	0	3/4	0	-
Recovery period																					
17 (48 h)		1/0	3/2	0	-	0	3	0	-	0	3	0	-	0	2/3	0	-	0	2	0	-
19 (96 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
21 (144 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1/2	0	-	0	1/2	0	-	0	2	0	-	0	1/2	0	-	0	1	0	-
27 (288 h)		0	1	0	-	0	1/2	0	-	0	2	0	-	0	1/0	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)		

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Females (196) E	Oe	I/H	F	(197) E	Oe	I/H	F	(198) E	Oe	I/H	F	(199) E	Oe	I/H	F	(200) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1/0	0	-	0	0/1	0	-	0	0	0	-	0	1/0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0/1	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	1	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	4/0	0	0	-	4	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	2	0	-	0	2/3	0	-	0	2/3	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding at left/right administration site, if different (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Females (201) E	Oe	I/H	F	(202) E	Oe	I/H	F	(203) E	Oe	I/H	F	(204) E	Oe	I/H	F	(205) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	0/1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	0/1	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	3/2	0	-	0	3	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	2	0	-	0	3	0	-	0	2/3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding at left/right administration site, if different (if applicable and different severities were noted)	S:	Scabby skin

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TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Females (206) E	Oe	I/H	F	(207) E	Oe	I/H	F	(208) E	Oe	I/H	F	(209) E	Oe	I/H	F	(210) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1/0	0	-	0	1	0	-	0	1/0	0	-	0	1	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0/1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1/0	0	-	0	0	0	-	0	1	0	-	0	0/1	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2/1	0	-	0	3/2	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	4	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3/4	0	-	0	3	0	-	0	2/3	0	-	0	3	0	-	0	3	0	-
Recovery period																					
17 (48 h)		1/0	2/3	0	-	0	1/2	0	-	0	1	0	-	1/0	2	0	-	0	2	0	-
19 (96 h)		0	2	0	-	0	0	0	-	0	0/1	0	-	0	2/1	0	-	0	2/1	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	0/1	0	-	0	2/1	0	-	0	2/1	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1/2	0	-	0	1/2	0	-
27 (288 h)		0	1	0	-	0	0/1	0	-	0	1	0	-	0	1/2	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding at left/right administration site, if different (if applicable and different severities were noted)		

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TABLE 2-1 Clinical Signs - Systemic Tolerance Rat
- Summary -

Observation Type: All Types Sex: Male From Day 1 (Start Date) to 38 (Start Date)	Group 1: Control	Group 2: 30 µg/ animal BNT162a1	Group 3: 10 µg/ animal BNT162a1	Group 4: 30 µg/ animal BNT162b1	Group 5: 100 µg/ animal BNT162b1	Group 6: 30 µg/ animal BNT162c1	Group 7: 100 µg/ animal BNT162b2
Normal							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	1 - 38	1 - 38	1 - 38	1 - 38	1 - 38	1 - 31	1 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	360	360	360	360	360	255	360
Scheduled Removal (Terminal)							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	17 - 38	17 - 38	17 - 38	17 - 38	17 - 38	10 - 31	17 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	15	15	15	15	15	15	15

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TABLE 2-1 Clinical Signs - Systemic Tolerance Rat
- Summary -

Observation Type: All Types Sex: Female From Day 1 (Start Date) to 38 (Start Date)	Group 1: Control	Group 2: 30 µg/ animal BNT162a1	Group 3: 10 µg/ animal BNT162a1	Group 4: 30 µg/ animal BNT162b1	Group 5: 100 µg/ animal BNT162b1	Group 6: 30 µg/ animal BNT162c1	Group 7: 100 µg/ animal BNT162b2
Normal							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	1 - 38	1 - 38	1 - 38	1 - 38	1 - 38	1 - 31	1 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	360	360	360	360	360	255	360
Scheduled Removal (Terminal)							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	17 - 38	17 - 38	17 - 38	17 - 38	17 - 38	10 - 31	17 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	15	15	15	15	15	15	15

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
2	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
3	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
4	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
5	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
6	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
7	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
8	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
9	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
10	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
11	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
12	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
13	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Document 1

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
14	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
15	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
1	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
2	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
3	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
4	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
5	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
6	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
7	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
8	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
9	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
10	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
11	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
12	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
13	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
14	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
15	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Document 1

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
31	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
32	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
33	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
34	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
35	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
36	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
37	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
38	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
39	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
40	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
41	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
42	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
43	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
44	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
45	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
31	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
32	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
33	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
34	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
35	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
36	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
37	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
38	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
39	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
40	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
41	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
42	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
43	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
44	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
45	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
61	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
62	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
63	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
64	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
65	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
66	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
67	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
68	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
69	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
70	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
71	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
72	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
73	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
74	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
75	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
61	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
62	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
63	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
64	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
65	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
66	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
67	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
68	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
69	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
70	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
71	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
72	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
73	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
74	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
75	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
91	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
92	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
93	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
94	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
95	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
96	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
97	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
98	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
99	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
100	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
101	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
102	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
103	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
104	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
105	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
91	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
92	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
93	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
94	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
95	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
96	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
97	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
98	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
99	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
100	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
101	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
102	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
103	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
104	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
105	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
121	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
122	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
123	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
124	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
125	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
126	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
127	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
128	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
129	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
130	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
131	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
132	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
133	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
134	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
135	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
121	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
122	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
123	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
124	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
125	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
126	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
127	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
128	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
129	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
130	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
131	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
132	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
133	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
134	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
135	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
151	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
152	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
153	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
154	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
155	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
156	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
157	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
158	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
159	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
160	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
161	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
162	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
163	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
164	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
165	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
151	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
152	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
153	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
154	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
155	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
156	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
157	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
158	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
159	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
160	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
161	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
162	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
163	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
164	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
165	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
181	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
182	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
183	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
184	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
185	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
186	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
187	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
188	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
189	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
190	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
191	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
192	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
193	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
194	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
195	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
181	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
182	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
183	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
184	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
185	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
186	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
187	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
188	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
189	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
190	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
191	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
192	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Document 1

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
193	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
194	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
195	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
16	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
17	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
18	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
19	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
20	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
21	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
22	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
23	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
24	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
25	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
26	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
27	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
28	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
29	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
30	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance - Individual Data - Rat

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
16	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
17	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
18	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
19	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
20	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
21	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
22	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
23	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
24	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
25	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
26	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
27	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
28	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
29	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
30	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Document 1

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
46	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
47	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
48	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
49	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
50	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
51	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
52	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
53	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
54	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
55	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
56	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
57	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
58	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
59	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
60	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
46	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
47	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
48	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
49	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
50	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
51	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
52	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
53	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
54	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
55	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
56	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
57	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Document 1

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
58	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
59	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
60	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
76	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
77	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
78	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
79	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
80	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
81	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
82	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
83	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
84	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
85	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
86	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
87	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
88	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
89	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
90	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
76	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
77	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
78	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
79	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
80	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
81	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
82	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
83	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
84	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
85	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
86	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
87	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
88	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
89	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
90	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
106	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
107	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
108	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
109	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
110	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
111	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
112	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
113	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
114	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
115	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
116	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
117	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
118	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
119	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
120	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
106	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
107	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
108	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
109	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
110	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
111	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
112	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
113	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
114	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
115	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
116	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
117	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
118	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
119	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
120	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
136	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
137	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
138	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
139	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
140	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
141	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
142	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
143	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
144	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
145	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
146	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
147	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
148	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
149	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
150	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
136	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
137	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
138	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
139	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
140	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
141	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
142	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
143	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
144	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
145	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
146	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
147	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
148	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
149	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
150	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
166	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
167	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
168	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
169	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
170	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
171	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
172	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
173	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
174	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
175	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
176	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
177	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
178	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
179	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
180	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance - Individual Data - Rat

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
166	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
167	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
168	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
169	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
170	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
171	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
172	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
173	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
174	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
175	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
176	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
177	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			

N=Normal; K=Scheduled Removal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
178	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
179	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
180	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			

N=Normal; K=Scheduled Removal

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RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
196	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
197	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
198	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
199	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
200	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
201	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
202	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
203	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
204	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
205	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
206	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
207	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

Three LNP-Formulated
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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
208	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
209	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
210	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
196	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
197	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
198	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
199	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
200	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
201	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
202	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
203	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
204	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
205	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
206	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
207	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Document 1

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
208	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
209	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			
210	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K			

N=Normal; K=Scheduled Removal

Document 1

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		-7 [a1]	-1 [a]	1 [a]	2 [a]	8 [a]	9 [a]	15 [a]
Group 1:	Mean	-	257.62	263.53	268.90	310.87	319.78	356.29
Control	SD	-	6.64	7.58	6.51	12.03	13.46	12.27
	N	-	15	15	15	15	15	15
		-	-	-	-	-	-	-
Group 2:	Mean	-	257.65	261.61	250.35**	293.50**	277.99**	315.29**
30 µg/	SD	-	6.69	6.31	8.19	8.11	9.29	16.84
animal	N	-	15	15	15	15	15	15
BNT162a1	%Diff	-	0.0	-0.7	-6.9	-5.6	-13.1	-11.5
Group 3:	Mean	258 94n	-	314 03**	303 03**	342 02**	323 25	363 25
10 µg/	SD	24 65	-	21 12	21 80	23 55	23 99	25 67
animal	N	15	-	15	15	15	15	15
BNT162a1	%Diff	-	-	19.2	12.7	10.0	1.1	2.0
Group 4:	Mean	-	257.79	263.16	256.27**	304.49	298.98*	337.96*
30 µg/	SD	-	6.87	5.64	5.36	7.53	8.06	13.00
animal	N	-	15	15	15	15	15	15
BNT162b1	%Diff	-	0.1	-0.1	-4.7	-2.1	-6.5	-5.1

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		-7	-1	1	2	8	9	15
Group 5:	Mean	256.81n	-	309.21**	281.83	321.17	298.54**	347.63
100 µg/	SD	17.84	-	19.73	19.55	20.99	24.02	26.28
animal	N	15	-	15	15	15	15	15
BNT162b1	%Diff	-	-	17.3	4.8	3.3	-6.6	-2.4
Group 6:	Mean	258.01n	-	308.23**	293.50**	325.49	305.99	348.50
30 µg/	SD	19.50	-	17.40	18.46	24.01	22.53	26.54
animal	N	15	-	15	15	15	15	5
BNT162c1	%Diff	-	-	17.0	9.1	4.7	-4.3	-2.2
Group 7:	Mean	257 88n	-	305 63**	283 37	317 95	293 24**	341 19
100 µg/	SD	19 55	-	20 51	22 56	20 59	21 98	21 54
animal	N	15	-	15	15	15	15	15
BNT162b2	%Diff	-	-	16.0	5.4	2.3	-8.3	-4.2

Anova & Dunnett: ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		16 [a]	18 [a1]	22 [a1]	25 [a1]	29 [a1]	30 [a1]	32 [a1]
Group 1:	Mean	361.27	362.44	380.10	385.68	409.78	-	418.86
Control	SD	11.98	13.75	19.57	16.43	15.77	-	12.26
	N	15	5	5	5	5	-	5
		-	-	-	-	-	-	-
Group 2:	Mean	301.04**	319.16*	343.06	360.54	392.18	-	398.86
30 µg/	SD	13.62	14.28	16.70	17.61	15.75	-	18.07
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-16.7	-11.9	-9.7	-6.5	-4.3	-	-4.8
Group 3:	Mean	351 17	368 34	389 26	410 54	422 70	-	426 70
10 µg/	SD	25 67	30 64	27 89	32 77	35 01	-	34 60
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-2.8	1.6	2.4	6.4	3.2	-	1.9
Group 4:	Mean	329.54**	354.12	374.26	389.04	410.94	-	420.22
30 µg/	SD	11.94	16.10	16.54	28.23	33.61	-	42.19
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	-8.8	-2.3	-1.5	0.9	0.3	-	0.3

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05

TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		16	18	22	25	29	30	32
Group 5:	Mean	327.82**	351.28	369.70	393.08	407.76	-	414.80
100 µg/	SD	28.27	23.29	24.59	29.03	28.89	-	28.04
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	-9.3	-3.1	-2.7	1.9	-0.5	-	-1.0
Group 6:	Mean	-	366.86	386.92	400.70	403.28	404.96 n	-
30 µg/	SD	-	35.54	36.88	33.35	27.03	30.01	-
animal	N	-	5	5	5	5	5	-
BNT162c1	%Diff	-	1.2	1.8	3.9	-1.6	-	-
Group 7:	Mean	320 31**	339 30	362 72	382 86	397 60	-	405 80
100 µg/	SD	22 86	27 06	24 85	26 36	26 87	-	29 28
animal	N	15	5	5	5	5	-	5
BNT162b2	%Diff	-11.3	-6.4	-4.6	-0.7	-3.0	-	-3.1

Anova & Dunnett: ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date	
		36	37
Group 1: Control	Mean	427.06	430.64
	SD	18.28	17.07
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	413.02	417.74
	SD	21.85	26.88
	N	5	5
	%Diff	-3.3	-3.0
Group 3: 10 µg/ animal BNT162a1	Mean	438 92	441 08
	SD	38 53	36 63
	N	5	5
	%Diff	2.8	2.4
Group 4: 30 µg/ animal BNT162b1	Mean	430.80	432.84
	SD	45.93	42.13
	N	5	5
	%Diff	0.9	0.5

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date	
		36	37
Group 5:	Mean	419.80	421.92
100 µg/	SD	25.11	27.60
animal	N	5	5
BNT162b1	%Diff	-1.7	-2.0
Group 6:	Mean	-	-
30 µg/	SD	-	-
animal	N	-	-
BNT162c1	%Diff	-	-
Group 7:	Mean	411 82	417 40
100 µg/	SD	31 28	28 42
animal	N	5	5
BNT162b2	%Diff	-3.6	-3.1

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		-7 [a1]	-1 [a]	1 [a]	2 [a]	8 [a]	9 [a]	15 [a]
Group 1:	Mean	-	213.78	212.25	215.06	231.69	236.97	249.79
Control	SD	-	9.13	9.41	10.81	12.12	13.24	13.90
	N	-	15	15	15	15	15	15
		-	-	-	-	-	-	-
Group 2:	Mean	-	213.85	209.60	205.43	229.60	221.53*	243.21
30 µg/	SD	-	9.08	11.06	9.87	11.80	11.92	10.42
animal	N	-	15	15	15	15	15	15
BNT162a1	%Diff	-	0.0	-1.3	-4.5	-0.9	-6.5	-2.6
Group 3:	Mean	190 83n	-	215 39	211 83	232 60	224 57	243 57
10 µg/	SD	20 28	-	18 50	17 58	20 46	19 61	22 86
animal	N	15	-	15	15	15	15	15
BNT162a1	%Diff	-	-	1.5	-1.5	0.4	-5.2	-2.5
Group 4:	Mean	-	214.15	213.98	214.20	234.73	234.26	258.37
30 µg/	SD	-	9.03	10.29	10.97	17.14	15.66	17.90
animal	N	-	15	15	15	15	15	15
BNT162b1	%Diff	-	0.2	0.8	-0.4	1.3	-1.1	3.4

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05
[a1] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		-7	-1	1	2	8	9	15
Group 5:	Mean	192.28n	-	214.81	204.95	234.26	222.42*	246.11
100 µg/	SD	18.07	-	17.07	14.94	16.46	17.02	19.58
animal	N	15	-	15	15	15	15	15
BNT162b1	%Diff	-	-	1.2	-4.7	1.1	-6.1	-1.5
Group 6:	Mean	193.47n	-	217.13	209.75	230.53	220.42**	237.84
30 µg/	SD	17.74	-	19.32	19.09	23.60	23.19	32.48
animal	N	15	-	15	15	15	15	5
BNT162c1	%Diff	-	-	2.3	-2.5	-0.5	-7.0	-4.8
Group 7:	Mean	192 57n	-	218 14	205 63	228 15	220 75*	238 23
100 µg/	SD	18 31	-	19 76	18 37	17 99	19 85	20 09
animal	N	15	-	15	15	15	15	15
BNT162b2	%Diff	-	-	2.8	-4.4	-1.5	-6.8	-4.6

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		16 [a]	18 [a1]	22 [a]	25 [a2]	29 [a1]	30 [a1]	32 [a1]
Group 1:	Mean	247.66	267.84	273.16	274.66	283.22	-	288.50
Control	SD	13.00	19.29	16.70	16.68	21.37	-	25.05
	N	15	5	5	5	5	-	5
		-	-	-	-	-	-	-
Group 2:	Mean	230.25**	249.48	255.86	263.70	274.06	-	278.90
30 µg/	SD	10.43	14.24	13.76	16.64	7.60	-	15.05
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-7.0	-6.9	-6.3	-4.0	-3.2	-	-3.3
Group 3:	Mean	238 89	251 48	254 12	259 62	272 38	-	272 52
10 µg/	SD	21 23	26 31	18 83	21 02	24 61	-	18 12
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-3.5	-6.1	-7.0	-5.5	-3.8	-	-5.5
Group 4:	Mean	250.33	266.42	270.98	272.64	285.28	-	287.32
30 µg/	SD	17.86	5.68	8.29	8.67	10.15	-	13.05
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	1.1	-0.5	-0.8	-0.7	0.7	-	-0.4

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Log)

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		16	18	22	25	29	30	32
Group 5:	Mean	236.60	248.36	259.16	274.44	276.78	-	274.96
100 µg/	SD	17.79	17.83	21.76	23.21	21.16	-	17.93
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	-4.5	-7.3	-5.1	-0.1	-2.3	-	-4.7
Group 6:	Mean	-	248.94	256.08	262.30	274.14	268.30 n	-
30 µg/	SD	-	30.16	33.99	32.06	32.12	32.09	-
animal	N	-	5	5	5	5	5	-
BNT162c1	%Diff	-	-7.1	-6.3	-4.5	-3.2	-	-
Group 7:	Mean	231 70**	238 60	245 28	254 14	264 86	-	268 56
100 µg/	SD	19 18	13 08	18 43	18 64	19 30	-	19 05
animal	N	15	5	5	5	5	-	5
BNT162b2	%Diff	-6.4	-10.9	-10.2	-7.5	-6.5	-	-6.9

Anova & Dunnett: ** = p ≤ 0.01; n - Inappropriate for statistics

TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date	
		36	37
Group 1: Control	Mean	299.72	296.84
	SD	26.90	29.87
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	285.70	288.34
	SD	16.50	19.50
	N	5	5
	%Diff	-4.7	-2.9
Group 3: 10 µg/ animal BNT162a1	Mean	275 70	277 00
	SD	20 21	21 68
	N	5	5
	%Diff	-8.0	-6.7
Group 4: 30 µg/ animal BNT162b1	Mean	294.12	289.40
	SD	10.23	12.11
	N	5	5
	%Diff	-1.9	-2.5

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date	
		36	37
Group 5:	Mean	283.10	283.22
100 µg/	SD	16.64	18.17
animal	N	5	5
BNT162b1	%Diff	-5.5	-4.6
Group 6:	Mean	-	-
30 µg/	SD	-	-
animal	N	-	-
BNT162c1	%Diff	-	-
Group 7:	Mean	274 54	266 64
100 µg/	SD	19 52	21 63
animal	N	5	5
BNT162b2	%Diff	-8.4	-10.2

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Weight	2	Male	2	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	8	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	9	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	15	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	3	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	3	Male	1	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	3	Male	2	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	3	Male	8	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	4	Male	2	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	4	Male	9	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Weight	4	Male	15	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Weight	2	Male	16	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	18	*	Anova & Dunnett: * = p ≤ 0.05
	Body Weight	4	Male	16	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	5	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	5	Male	1	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	5	Male	9	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	6	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	6	Male	1	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	6	Male	2	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	7	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Male	1	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	7	Male	9	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	5	Male	16	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	6	Male	30	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Male	16	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 3-1 Body Weight - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Weight	2	Female	9	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Weight	3	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	2	Female	16	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	5	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	5	Female	9	*	Anova & Dunnett: * = p ≤ 0.05
	Body Weight	6	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	6	Female	9	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	7	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Female	9	*	Anova & Dunnett: * = p ≤ 0.05
	Body Weight	6	Female	30	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Female	16	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
1	-	251.8	258.8	263.2	303.8	313.1	350.3
2	-	255.5	259.7	261.3	303.8	307.1	340.3
3	-	256.1	262.9	271.5	322.0	329.2	371.3
4	-	261.1	266.1	275.6	316.1	323.3	358.0
5	-	253.1	262.7	268.2	314.1	318.6	346.0
6	-	257.7	264.3	272.2	314.7	322.4	373.9
7	-	250.8	258.6	266.8	308.0	319.4	351.8
8	-	266.4	273.3	275.7	318.5	329.4	360.0
9	-	250.2	255.1	262.8	317.2	327.9	373.7
10	-	268.4	274.2	277.0	328.5	341.0	366.7
11	-	267.7	270.9	276.9	316.6	325.9	355.0
12	-	249.1	254.8	261.4	279.1	286.3	341.9
13	-	264.4	278.4	275.4	317.4	330.6	363.0
14	-	252.5	254.9	257.8	295.4	301.5	334.6
15	-	259.5	258.3	267.7	307.8	321.0	357.8
Mean	-	257.62	263.53	268.90	310.87	319.78	356.29
SD	-	6.64	7.58	6.51	12.03	13.46	12.27
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
1	351.1	-	-	-	-	-	-
2	345.4	-	-	-	-	-	-
3	376.9	-	-	-	-	-	-
4	361.8	-	-	-	-	-	-
5	351.3	-	-	-	-	-	-
6	377.6	-	-	-	-	-	-
7	355.6	-	-	-	-	-	-
8	365.0	-	-	-	-	-	-
9	375.6	-	-	-	-	-	-
10	369.6	-	-	-	-	-	-
11	364.2	365.0	377.9	385.3	412.9	416.5	419.9
12	352.6	351.8	373.8	371.2	397.0	414.3	424.7
13	365.6	375.5	396.4	404.0	425.8	431.8	443.4
14	337.6	344.9	351.8	367.7	390.1	401.9	401.4
15	369.1	375.0	400.6	400.2	423.1	429.8	445.9
Mean	361.27	362.44	380.10	385.68	409.78	418.86	427.06
SD	11.98	13.75	19.57	16.43	15.77	12.26	18.28
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date
	37
1	-
2	-
3	-
4	-
5	-
6	-
7	-
8	-
9	-
10	-
11	425.1
12	431.7
13	443.1
14	404.9
15	448.4
Mean	430.64
SD	17.07
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
31	-	265.3	270.3	257.9	285.4	268.0	310.1
32	-	253.3	258.0	231.7	292.3	271.2	303.0
33	-	257.9	256.1	253.0	305.1	289.7	347.2
34	-	267.6	272.2	258.8	301.9	284.1	315.0
35	-	256.2	263.5	251.9	295.0	281.3	321.2
36	-	249.9	253.9	242.5	289.2	278.6	309.8
37	-	268.5	267.1	253.3	293.2	279.6	316.5
38	-	265.7	269.6	262.1	309.9	284.7	326.8
39	-	249.2	259.9	239.5	279.8	257.3	269.7
40	-	260.7	266.7	257.3	291.2	276.2	307.7
41	-	255.8	258.5	250.3	291.8	286.3	316.7
42	-	260.1	260.2	252.7	288.1	273.5	309.5
43	-	252.6	260.8	254.3	298.0	292.1	330.8
44	-	250.7	252.8	245.2	283.8	267.7	317.4
45	-	251.2	254.5	244.7	297.8	279.5	327.9
Mean	-	257.65	261.61	250.35	293.50	277.99	315.29
SD	-	6.69	6.31	8.19	8.11	9.29	16.84
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
31	291.4	-	-	-	-	-	-
32	293.6	-	-	-	-	-	-
33	319.2	-	-	-	-	-	-
34	303.9	-	-	-	-	-	-
35	306.5	-	-	-	-	-	-
36	300.7	-	-	-	-	-	-
37	305.1	-	-	-	-	-	-
38	313.2	-	-	-	-	-	-
39	260.9	-	-	-	-	-	-
40	293.9	-	-	-	-	-	-
41	304.0	312.3	329.6	343.6	377.1	382.2	392.3
42	297.5	309.0	331.4	347.5	379.0	380.9	398.7
43	315.1	344.3	370.3	388.5	415.6	424.7	448.1
44	304.9	315.1	336.8	361.5	390.7	403.4	408.3
45	305.7	315.1	347.2	361.6	398.5	403.1	417.7
Mean	301.04	319.16	343.06	360.54	392.18	398.86	413.02
SD	13.62	14.28	16.70	17.61	15.75	18.07	21.85
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
31	-
32	-
33	-
34	-
35	-
36	-
37	-
38	-
39	-
40	-
41	393.2
42	399.6
43	461.4
44	412.1
45	422.4
Mean	417.74
SD	26.88
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
61	286.5	-	341.7	327.9	365.9	353.3	395.8
62	222.3	-	290.4	273.7	315.6	289.4	331.6
63	287.6	-	335.3	339.7	365.9	352.1	388.5
64	272.1	-	316.1	303.4	336.8	317.0	352.4
65	229.0	-	293.2	285.3	332.7	316.1	361.4
66	296.9	-	338.8	320.6	344.0	331.6	367.0
67	278.5	-	335.8	324.9	375.7	351.3	394.9
68	231.8	-	285.5	266.6	304.4	280.0	314.8
69	234.6	-	295.0	286.4	315.4	302.6	345.1
70	269.0	-	332.3	322.1	369.0	344.2	381.6
71	246.4	-	300.4	292.8	339.3	321.4	363.1
72	238.8	-	296.1	288.6	322.4	311.7	349.8
73	243.0	-	292.2	287.6	318.1	297.2	330.8
74	274.4	-	331.1	315.9	360.2	333.9	378.6
75	273.2	-	326.5	309.9	364.9	347.0	393.3
Mean	258.94	-	314.03	303.03	342.02	323.25	363.25
SD	24.65	-	21.12	21.80	23.55	23.99	25.67
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
61	377.1	-	-	-	-	-	-
62	325.2	-	-	-	-	-	-
63	374.3	-	-	-	-	-	-
64	348.8	-	-	-	-	-	-
65	355.0	-	-	-	-	-	-
66	347.0	-	-	-	-	-	-
67	382.7	-	-	-	-	-	-
68	296.6	-	-	-	-	-	-
69	335.0	-	-	-	-	-	-
70	369.8	-	-	-	-	-	-
71	342.9	356.1	380.7	399.9	416.1	423.9	445.2
72	338.0	347.0	373.3	385.5	395.4	394.9	406.6
73	319.4	337.5	356.2	378.4	385.0	391.7	393.4
74	372.7	392.7	414.0	433.9	450.5	453.7	464.2
75	383.0	408.4	422.1	455.0	466.5	469.3	485.2
Mean	351.17	368.34	389.26	410.54	422.70	426.70	438.92
SD	25.67	30.64	27.89	32.77	35.01	34.60	38.53
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
61	-
62	-
63	-
64	-
65	-
66	-
67	-
68	-
69	-
70	-
71	447.4
72	406.5
73	400.7
74	466.9
75	483.9
Mean	441.08
SD	36.63
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
91	-	255.7	258.5	255.6	301.2	300.0	334.8
92	-	250.0	257.6	250.4	300.2	293.9	321.0
93	-	249.3	259.3	254.0	306.4	298.2	335.4
94	-	250.2	257.8	253.6	290.9	286.3	316.8
95	-	255.0	263.7	252.3	298.1	299.8	335.7
96	-	267.5	272.8	263.4	317.5	311.9	365.4
97	-	259.5	261.0	253.5	300.1	290.6	336.6
98	-	250.8	254.9	252.0	295.7	293.0	328.0
99	-	267.8	268.3	264.3	312.4	309.1	351.1
100	-	268.9	271.6	261.4	307.7	293.0	332.1
101	-	264.1	269.1	260.2	306.7	302.5	326.7
102	-	252.4	258.3	247.0	298.1	290.1	341.4
103	-	257.5	263.0	260.1	313.6	313.3	356.2
104	-	261.9	268.3	263.1	312.5	301.0	344.4
105	-	256.3	263.2	253.2	306.2	302.0	343.8
Mean	-	257.79	263.16	256.27	304.49	298.98	337.96
SD	-	6.87	5.64	5.36	7.53	8.06	13.00
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
91	329.1	-	-	-	-	-	-
92	315.9	-	-	-	-	-	-
93	323.2	-	-	-	-	-	-
94	319.3	-	-	-	-	-	-
95	326.7	-	-	-	-	-	-
96	352.5	-	-	-	-	-	-
97	324.5	-	-	-	-	-	-
98	322.1	-	-	-	-	-	-
99	342.5	-	-	-	-	-	-
100	318.1	-	-	-	-	-	-
101	321.5	332.2	358.3	356.4	372.2	367.6	383.9
102	331.1	353.2	362.2	380.7	394.9	402.9	398.3
103	355.5	377.3	400.3	433.8	460.7	482.0	500.5
104	332.5	357.0	372.6	382.5	401.8	414.3	423.9
105	328.6	350.9	377.9	391.8	425.1	434.3	447.4
Mean	329.54	354.12	374.26	389.04	410.94	420.22	430.80
SD	11.94	16.10	16.54	28.23	33.61	42.19	45.93
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
91	-
92	-
93	-
94	-
95	-
96	-
97	-
98	-
99	-
100	-
101	391.9
102	403.8
103	500.3
104	430.5
105	437.7
Mean	432.84
SD	42.13
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
121	275.7	-	333.6	301.4	338.0	319.2	371.4
122	243.8	-	292.5	261.7	294.8	271.8	311.6
123	236.5	-	292.5	268.3	314.2	299.2	345.9
124	274.7	-	332.5	320.5	361.3	349.7	401.8
125	239.3	-	293.2	272.2	298.2	281.4	323.1
126	273.4	-	326.7	297.6	336.7	321.4	374.8
127	241.4	-	292.9	261.3	308.9	284.6	335.2
128	239.9	-	287.7	256.4	301.4	271.8	322.6
129	269.8	-	313.6	285.6	325.7	301.5	340.2
130	238.0	-	290.8	265.7	310.1	283.9	343.8
131	281.9	-	343.9	306.3	350.7	326.5	380.4
132	248.1	-	297.0	275.0	309.0	280.0	331.6
133	241.6	-	292.6	267.3	297.5	270.2	317.3
134	278.5	-	327.4	298.9	342.0	319.5	368.2
135	269.6	-	321.3	289.2	329.0	297.4	346.5
Mean	256.81	-	309.21	281.83	321.17	298.54	347.63
SD	17.84	-	19.73	19.55	20.99	24.02	26.28
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
121	359.4	-	-	-	-	-	-
122	296.4	-	-	-	-	-	-
123	328.9	-	-	-	-	-	-
124	387.5	-	-	-	-	-	-
125	310.9	-	-	-	-	-	-
126	359.7	-	-	-	-	-	-
127	314.8	-	-	-	-	-	-
128	291.3	-	-	-	-	-	-
129	319.8	-	-	-	-	-	-
130	318.3	-	-	-	-	-	-
131	354.9	381.6	402.1	435.6	445.7	458.3	452.3
132	305.3	332.5	348.1	375.2	378.8	403.6	409.1
133	294.9	326.3	344.3	362.4	380.3	385.1	392.4
134	346.6	367.6	385.7	408.0	425.2	424.5	439.7
135	328.6	348.4	368.3	384.2	408.8	402.5	405.5
Mean	327.82	351.28	369.70	393.08	407.76	414.80	419.80
SD	28.27	23.29	24.59	29.03	28.89	28.04	25.11
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
121	-
122	-
123	-
124	-
125	-
126	-
127	-
128	-
129	-
130	-
131	461.8
132	407.9
133	391.7
134	437.1
135	411.1
Mean	421.92
SD	27.60
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	-7	1	2	8	9	15	18
151	244.4	291.9	280.0	305.1	285.3	-	-
152	294.0	337.0	319.8	347.9	329.4	-	-
153	239.2	290.7	272.2	292.7	280.1	-	-
154	238.9	298.0	293.1	327.1	308.0	-	-
155	247.2	310.0	295.4	329.5	316.4	-	-
156	247.7	300.5	292.7	318.5	297.2	-	-
157	275.5	326.4	310.7	348.9	330.5	-	-
158	244.5	292.2	269.5	287.6	272.4	-	-
159	242.5	296.7	292.4	321.5	312.9	-	-
160	242.4	286.1	264.9	299.7	274.6	-	-
161	285.9	337.3	322.4	356.2	331.0	367.7	396.5
162	242.8	296.1	275.9	306.6	286.1	312.5	318.0
163	277.5	324.3	308.9	355.6	336.0	369.9	394.3
164	269.6	315.8	292.0	326.2	300.4	327.7	340.4
165	278.1	320.5	312.6	359.2	329.6	364.7	385.1
Mean	258.01	308.23	293.50	325.49	305.99	348.50	366.86
SD	19.50	17.40	18.46	24.01	22.53	26.54	35.54
N	15	15	15	15	15	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	22	25	29	30
151	-	-	-	-
152	-	-	-	-
153	-	-	-	-
154	-	-	-	-
155	-	-	-	-
156	-	-	-	-
157	-	-	-	-
158	-	-	-	-
159	-	-	-	-
160	-	-	-	-
161	408.2	410.5	407.4	413.9
162	335.3	356.1	367.7	361.7
163	412.6	425.8	424.8	429.3
164	360.5	376.5	384.5	387.5
165	418.0	434.6	432.0	432.4
Mean	386.92	400.70	403.28	404.96
SD	36.88	33.35	27.03	30.01
N	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
181	283.0	-	338.3	327.4	355.2	332.4	371.5
182	245.6	-	291.8	262.7	299.9	273.2	318.0
183	244.2	-	301.1	270.6	320.6	293.3	342.7
184	236.4	-	288.7	264.9	305.9	283.2	329.4
185	281.3	-	336.7	307.0	347.7	314.0	375.5
186	242.7	-	275.7	253.9	291.6	257.4	307.3
187	277.3	-	324.9	296.5	334.2	298.7	346.2
188	241.5	-	291.4	270.2	307.1	284.6	342.6
189	247.9	-	297.8	271.8	304.8	275.6	327.6
190	241.6	-	291.1	267.3	308.9	290.6	339.2
191	247.5	-	293.4	276.0	303.5	280.1	327.8
192	284.5	-	325.2	305.0	334.6	317.3	361.7
193	282.3	-	326.2	313.3	341.0	322.4	365.4
194	237.3	-	283.5	263.7	289.8	266.3	309.3
195	275.1	-	318.6	300.3	324.5	309.5	353.6
Mean	257.88	-	305.63	283.37	317.95	293.24	341.19
SD	19.55	-	20.51	22.56	20.59	21.98	21.54
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
181	353.6	-	-	-	-	-	-
182	294.8	-	-	-	-	-	-
183	320.2	-	-	-	-	-	-
184	307.8	-	-	-	-	-	-
185	348.7	-	-	-	-	-	-
186	290.5	-	-	-	-	-	-
187	318.9	-	-	-	-	-	-
188	316.9	-	-	-	-	-	-
189	308.8	-	-	-	-	-	-
190	322.2	-	-	-	-	-	-
191	307.9	314.8	339.3	362.8	376.8	387.6	392.3
192	345.9	356.7	379.1	398.4	407.4	419.4	430.0
193	354.6	366.3	385.1	411.8	425.3	435.7	440.6
194	282.3	305.9	332.3	348.3	362.3	364.0	366.5
195	331.5	352.8	377.8	393.0	416.2	422.3	429.7
Mean	320.31	339.30	362.72	382.86	397.60	405.80	411.82
SD	22.86	27.06	24.85	26.36	26.87	29.28	31.28
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date
	37
181	-
182	-
183	-
184	-
185	-
186	-
187	-
188	-
189	-
190	-
191	403.6
192	427.4
193	444.9
194	374.7
195	436.4
Mean	417.40
SD	28.42
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
16	-	226.6	219.9	230.2	249.9	246.3	268.1
17	-	204.0	199.0	206.0	235.3	246.8	243.4
18	-	200.6	199.3	204.0	211.8	220.4	235.4
19	-	205.9	206.3	207.3	220.9	223.7	243.3
20	-	220.0	215.5	214.7	230.5	229.6	245.8
21	-	207.2	203.0	204.5	229.6	226.6	235.7
22	-	202.2	203.8	205.6	217.9	226.3	232.7
23	-	209.0	205.9	208.8	221.8	227.8	242.1
24	-	210.3	212.6	217.6	231.9	237.2	252.3
25	-	219.3	213.9	217.3	238.0	238.9	248.5
26	-	219.7	217.8	215.8	225.7	226.6	241.4
27	-	226.2	231.2	239.7	249.8	266.5	279.8
28	-	227.8	224.5	226.0	253.8	258.4	268.2
29	-	212.5	211.7	205.2	229.8	239.0	246.7
30	-	215.4	219.4	223.2	228.7	240.5	263.4
Mean	-	213.78	212.25	215.06	231.69	236.97	249.79
SD	-	9.13	9.41	10.81	12.12	13.24	13.90
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
16	269.6	-	-	-	-	-	-
17	242.1	-	-	-	-	-	-
18	235.8	-	-	-	-	-	-
19	236.9	-	-	-	-	-	-
20	246.6	-	-	-	-	-	-
21	238.7	-	-	-	-	-	-
22	231.1	-	-	-	-	-	-
23	242.4	-	-	-	-	-	-
24	255.8	-	-	-	-	-	-
25	250.6	-	-	-	-	-	-
26	238.7	242.7	260.6	252.0	256.7	253.0	270.6
27	264.6	293.9	298.1	295.9	310.7	312.0	320.7
28	273.8	272.6	281.4	285.0	297.4	312.3	332.6
29	238.5	256.7	257.6	269.4	270.5	277.1	276.9
30	249.7	273.3	268.1	271.0	280.8	288.1	297.8
Mean	247.66	267.84	273.16	274.66	283.22	288.50	299.72
SD	13.00	19.29	16.70	16.68	21.37	25.05	26.90
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date
	37
16	-
17	-
18	-
19	-
20	-
21	-
22	-
23	-
24	-
25	-
26	262.9
27	321.3
28	334.5
29	281.5
30	284.0
Mean	296.84
SD	29.87
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
46	-	226.6	224.6	217.0	241.8	235.0	245.7
47	-	216.7	215.5	205.2	235.7	231.3	239.6
48	-	208.1	205.0	203.7	228.9	228.3	258.4
49	-	219.5	210.7	206.9	227.5	211.0	241.7
50	-	216.0	215.5	206.9	220.4	224.1	243.8
51	-	208.9	200.8	193.6	228.6	203.6	227.9
52	-	200.6	194.0	193.9	218.5	218.6	255.4
53	-	204.0	192.6	194.1	220.9	212.8	237.3
54	-	213.0	213.4	204.3	229.8	218.7	233.0
55	-	202.5	203.5	195.9	225.3	211.6	231.6
56	-	204.7	193.0	195.0	216.6	212.7	235.7
57	-	212.3	211.5	207.5	232.1	227.6	248.8
58	-	225.5	224.6	224.8	242.6	231.4	253.7
59	-	228.6	215.9	217.6	259.8	247.3	261.4
60	-	220.8	223.4	215.1	215.5	208.9	234.1
Mean	-	213.85	209.60	205.43	229.60	221.53	243.21
SD	-	9.08	11.06	9.87	11.80	11.92	10.42
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
46	233.6	-	-	-	-	-	-
47	233.4	-	-	-	-	-	-
48	253.4	-	-	-	-	-	-
49	224.8	-	-	-	-	-	-
50	234.5	-	-	-	-	-	-
51	212.2	-	-	-	-	-	-
52	232.1	-	-	-	-	-	-
53	217.0	-	-	-	-	-	-
54	223.7	-	-	-	-	-	-
55	223.1	-	-	-	-	-	-
56	222.5	232.8	236.6	253.6	277.0	284.4	276.8
57	234.3	256.2	258.8	261.0	269.7	266.9	271.8
58	237.7	258.5	271.8	287.2	278.4	291.6	302.9
59	243.7	264.2	263.9	272.3	282.1	292.4	304.4
60	227.8	235.7	248.2	244.4	263.1	259.2	272.6
Mean	230.25	249.48	255.86	263.70	274.06	278.90	285.70
SD	10.43	14.24	13.76	16.64	7.60	15.05	16.50
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
46	-
47	-
48	-
49	-
50	-
51	-
52	-
53	-
54	-
55	-
56	280.6
57	270.1
58	314.9
59	302.6
60	273.5
Mean	288.34
SD	19.50
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
76	182.3	-	205.4	194.0	226.0	212.1	245.1
77	194.8	-	225.0	219.6	238.5	229.4	242.5
78	176.3	-	202.6	195.0	220.1	214.5	232.7
79	168.7	-	247.4	242.7	264.6	257.9	284.8
80	168.7	-	193.5	188.7	199.8	197.6	206.5
81	180.6	-	204.9	207.7	243.9	231.2	229.2
82	238.1	-	249.8	240.3	279.4	268.1	279.1
83	195.6	-	206.1	208.1	228.8	217.1	231.3
84	184.8	-	201.0	202.2	219.6	210.8	235.6
85	191.5	-	208.5	213.4	227.7	214.9	236.2
86	192.5	-	215.4	206.7	221.8	218.6	225.8
87	183.2	-	211.3	205.0	228.6	219.1	274.1
88	231.8	-	245.5	240.2	252.5	249.0	269.7
89	199.2	-	218.1	219.4	225.7	221.3	237.7
90	174.4	-	196.3	194.4	212.0	206.9	223.2
Mean	190.83	-	215.39	211.83	232.60	224.57	243.57
SD	20.28	-	18.50	17.58	20.46	19.61	22.86
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
76	238.3	-	-	-	-	-	-
77	233.1	-	-	-	-	-	-
78	220.6	-	-	-	-	-	-
79	279.3	-	-	-	-	-	-
80	210.1	-	-	-	-	-	-
81	234.9	-	-	-	-	-	-
82	278.9	-	-	-	-	-	-
83	228.7	-	-	-	-	-	-
84	231.4	-	-	-	-	-	-
85	231.1	-	-	-	-	-	-
86	222.0	235.8	238.3	244.2	252.5	253.4	259.7
87	257.5	287.5	268.8	275.4	285.9	293.2	287.0
88	263.3	267.6	278.6	286.9	304.5	288.3	305.0
89	235.3	245.5	248.8	254.6	275.0	271.6	270.1
90	218.8	221.0	236.1	237.0	244.0	256.1	256.7
Mean	238.89	251.48	254.12	259.62	272.38	272.52	275.70
SD	21.23	26.31	18.83	21.02	24.61	18.12	20.21
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
76	-
77	-
78	-
79	-
80	-
81	-
82	-
83	-
84	-
85	-
86	260.6
87	292.5
88	306.2
89	270.5
90	255.2
Mean	277.00
SD	21.68
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
106	-	203.8	203.8	201.3	224.4	220.7	262.9
107	-	225.3	225.6	226.0	246.9	241.9	252.9
108	-	207.8	201.4	198.8	232.1	227.7	242.0
109	-	223.3	219.9	222.4	260.5	266.6	299.4
110	-	218.0	215.6	215.8	214.8	224.3	249.5
111	-	227.7	228.5	234.4	252.8	255.4	267.5
112	-	203.8	198.7	194.8	197.6	217.5	227.3
113	-	215.2	221.1	218.8	256.8	252.1	283.4
114	-	200.3	202.4	203.5	222.9	219.2	247.3
115	-	205.8	200.0	207.6	225.7	216.8	240.6
116	-	209.8	215.8	220.4	230.5	234.8	265.7
117	-	215.0	215.7	214.2	230.8	224.7	250.1
118	-	210.2	213.0	215.0	252.7	251.3	271.3
119	-	226.4	226.6	218.8	233.4	227.9	257.1
120	-	219.8	221.6	221.2	239.1	233.0	258.5
Mean	-	214.15	213.98	214.20	234.73	234.26	258.37
SD	-	9.03	10.29	10.97	17.14	15.66	17.90
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
106	254.3	-	-	-	-	-	-
107	248.6	-	-	-	-	-	-
108	236.8	-	-	-	-	-	-
109	296.8	-	-	-	-	-	-
110	250.0	-	-	-	-	-	-
111	265.8	-	-	-	-	-	-
112	226.0	-	-	-	-	-	-
113	271.6	-	-	-	-	-	-
114	231.5	-	-	-	-	-	-
115	240.6	-	-	-	-	-	-
116	246.1	273.3	275.2	270.5	281.2	289.6	293.8
117	243.5	261.6	268.5	260.1	274.0	274.7	283.9
118	261.6	262.9	277.0	284.2	300.6	308.0	309.7
119	241.6	271.9	276.7	274.4	289.4	286.4	297.0
120	240.2	262.4	257.5	274.0	281.2	277.9	286.2
Mean	250.33	266.42	270.98	272.64	285.28	287.32	294.12
SD	17.86	5.68	8.29	8.67	10.15	13.05	10.23
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
106	-
107	-
108	-
109	-
110	-
111	-
112	-
113	-
114	-
115	-
116	291.7
117	283.0
118	307.0
119	291.0
120	274.3
Mean	289.40
SD	12.11
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
136	191.5	-	218.3	210.2	240.9	231.4	271.9
137	192.7	-	206.1	195.5	233.8	218.7	240.4
138	194.9	-	204.1	201.7	214.0	208.4	225.0
139	183.5	-	214.7	203.8	230.5	226.7	238.3
140	182.0	-	196.2	192.2	216.2	204.9	222.1
141	233.9	-	249.4	234.2	264.7	254.9	263.7
142	182.2	-	203.6	194.6	227.5	210.2	234.1
143	175.9	-	207.7	199.9	225.1	218.9	257.7
144	183.3	-	214.1	197.4	247.6	230.5	277.5
145	229.5	-	248.3	236.9	269.0	254.7	270.3
146	174.2	-	189.5	185.0	215.5	194.8	212.0
147	198.2	-	219.4	205.1	226.4	217.0	237.2
148	172.0	-	202.2	190.6	224.9	208.5	245.0
149	191.8	-	220.1	211.0	241.2	233.7	257.6
150	198.6	-	228.4	216.2	236.6	223.0	238.8
Mean	192.28	-	214.81	204.95	234.26	222.42	246.11
SD	18.07	-	17.07	14.94	16.46	17.02	19.58
N	15	-	15	15	15	15	15

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
136	262.1	-	-	-	-	-	-
137	227.5	-	-	-	-	-	-
138	216.9	-	-	-	-	-	-
139	243.1	-	-	-	-	-	-
140	220.4	-	-	-	-	-	-
141	248.3	-	-	-	-	-	-
142	224.7	-	-	-	-	-	-
143	251.9	-	-	-	-	-	-
144	253.5	-	-	-	-	-	-
145	263.3	-	-	-	-	-	-
146	203.0	234.3	257.5	275.8	259.8	260.7	262.0
147	231.8	242.9	249.4	255.2	266.5	261.5	276.8
148	223.8	232.3	240.9	261.2	265.3	269.2	280.1
149	248.4	274.9	296.6	313.7	312.2	304.1	307.0
150	230.3	257.4	251.4	266.3	280.1	279.3	289.6
Mean	236.60	248.36	259.16	274.44	276.78	274.96	283.10
SD	17.79	17.83	21.76	23.21	21.16	17.93	16.64
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
136	-
137	-
138	-
139	-
140	-
141	-
142	-
143	-
144	-
145	-
146	261.3
147	276.6
148	275.8
149	308.1
150	294.3
Mean	283.22
SD	18.17
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	-7	1	2	8	9	15	18
166	193.9	207.4	212.1	227.3	219.8	-	-
167	186.6	219.3	206.4	233.9	224.7	-	-
168	172.2	201.4	184.5	199.8	196.7	-	-
169	197.5	209.9	212.1	240.6	226.4	-	-
170	231.7	252.7	245.3	260.8	255.6	-	-
171	199.4	204.3	213.0	199.9	217.1	-	-
172	197.5	214.4	209.8	227.7	208.9	-	-
173	191.0	230.1	213.3	229.0	209.1	-	-
174	185.0	215.6	202.4	222.5	213.0	-	-
175	181.6	216.2	203.2	236.8	221.7	-	-
176	194.7	197.4	195.2	216.6	200.2	214.6	225.3
177	186.6	206.4	209.8	223.3	213.2	238.9	269.3
178	180.5	206.0	193.5	223.0	209.1	217.0	221.7
179	171.9	208.5	189.4	220.3	203.5	225.3	237.2
180	231.9	267.3	256.3	296.5	287.3	293.4	291.2
Mean	193.47	217.13	209.75	230.53	220.42	237.84	248.94
SD	17.74	19.32	19.09	23.60	23.19	32.48	30.16
N	15	15	15	15	15	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	22	25	29	30
166	-	-	-	-
167	-	-	-	-
168	-	-	-	-
169	-	-	-	-
170	-	-	-	-
171	-	-	-	-
172	-	-	-	-
173	-	-	-	-
174	-	-	-	-
175	-	-	-	-
176	234.1	247.4	255.9	251.5
177	253.2	263.1	265.9	265.7
178	235.8	236.6	253.6	242.0
179	241.9	247.3	264.5	258.8
180	315.4	317.1	330.8	323.5
Mean	256.08	262.30	274.14	268.30
SD	33.99	32.06	32.12	32.09
N	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
196	230.6	-	241.3	232.0	247.8	246.3	271.6
197	182.6	-	199.0	195.1	219.5	207.3	210.8
198	171.6	-	196.5	187.2	217.2	207.6	223.7
199	182.0	-	204.8	180.1	211.1	197.1	228.9
200	235.1	-	264.2	245.2	266.6	259.2	274.7
201	188.8	-	214.8	198.7	229.5	220.8	248.2
202	186.3	-	208.0	196.6	221.7	209.4	213.0
203	198.3	-	227.5	209.9	235.0	228.9	245.4
204	199.6	-	237.1	228.5	251.0	253.4	248.1
205	196.3	-	227.6	212.7	234.7	228.3	245.2
206	179.0	-	208.4	194.5	213.0	203.4	232.0
207	193.8	-	215.6	202.9	219.1	212.6	233.8
208	174.6	-	188.3	185.7	195.1	194.3	211.7
209	182.6	-	210.9	200.5	223.0	214.7	228.9
210	187.3	-	228.1	214.9	237.9	227.9	257.5
Mean	192.57	-	218.14	205.63	228.15	220.75	238.23
SD	18.31	-	19.76	18.37	17.99	19.85	20.09
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
196	270.2	-	-	-	-	-	-
197	215.4	-	-	-	-	-	-
198	215.2	-	-	-	-	-	-
199	210.2	-	-	-	-	-	-
200	265.5	-	-	-	-	-	-
201	227.1	-	-	-	-	-	-
202	215.1	-	-	-	-	-	-
203	238.2	-	-	-	-	-	-
204	256.7	-	-	-	-	-	-
205	231.4	-	-	-	-	-	-
206	217.7	231.3	236.5	246.3	255.8	262.7	263.5
207	230.8	245.3	247.7	256.7	268.8	271.9	277.7
208	216.2	221.3	220.4	229.3	238.6	240.8	248.9
209	225.1	239.6	251.7	258.0	270.3	274.3	282.0
210	240.7	255.5	270.1	280.4	290.8	293.1	300.6
Mean	231.70	238.60	245.28	254.14	264.86	268.56	274.54
SD	19.18	13.08	18.43	18.64	19.30	19.05	19.52
N	15	5	5	5	5	5	5

TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date
	37
196	-
197	-
198	-
199	-
200	-
201	-
202	-
203	-
204	-
205	-
206	253.5
207	273.8
208	238.8
209	271.3
210	295.8
Mean	266.64
SD	21.63
N	5

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 1: Control	Mean	2.06	17.97	21.34	35.25	37.14	1.29	6.19
	SD	1.33	3.46	3.76	4.75	4.80	1.26	2.26
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	-4.30	12.23	6.31	20.60	15.14	4.46	12.27
	SD	2.23	3.49	4.18	7.32	6.02	2.72	3.47
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	-3 51	8 94	2 93	15 71	11 87	4 84	10 86
	SD	1 94	3 06	3 14	4 06	4 61	1 57	0 53
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	-2.61	15.71	13.63	28.43	25.24	6.06	12.10
	SD	1.19	1.83	2.60	4.14	4.20	1.59	2.03
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	-8.87	3.88	-3.50	12.41	5.95	7.83	13.49
	SD	1.89	2.37	3.52	4.18	4.68	1.97	2.11
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
Group 6:	Mean	-4.79	5.54	-0.77	10.03	15.69	22.03	26.48
30 µg/	SD	2.10	3.57	3.63	0.87	3.43	3.63	3.18
animal	N	15	15	15	5	5	5	5
BNT162c1		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 7:	Mean	-7.34	4.06	-4.07	11.69	4.82	4.69	12.02
100 µg/	SD	2.02	1.61	2.59	2.88	3.41	2.59	3.78
animal	N	15	15	15	15	15	5	5
BNT162b2		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 1: Control	Mean	7.78	14.52	17.09	19.35	20.35
	SD	2.20	1.57	1.80	2.43	2.22
	N	5	5	5	5	5
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	18.00	28.37	30.54	35.16	36.68
	SD	3.69	3.00	3.62	4.80	6.31
	N	5	5	5	5	5
		-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	16 87	20 31	21 47	24 91	25 56
	SD	1 90	1 92	2 68	3 60	3 64
	N	5	5	5	5	5
		-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	16.43	22.97	25.68	28.83	29.45
	SD	4.31	6.22	8.45	9.49	7.98
	N	5	5	5	5	5
		-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	20.63	25.14	27.38	28.95	29.55
	SD	3.04	2.37	4.60	4.47	3.84
	N	5	5	5	5	5
		-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date	
		9 → 29	9 → 30
Group 6:	Mean	27.42	27.88
30 µg/	SD	2.94	2.36
animal	N	5	5
BNT162c1		-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 7:	Mean	18.21	22.80	25.27	27.09	28.90
100 µg/	SD	3.18	4.24	3.17	2.73	4.10
animal	N	5	5	5	5	5
BNT162b2		-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 1: Control	Mean	1.32	9.19	11.67	17.66	16.70	5.88	8.00
	SD	1.94	3.95	4.48	3.15	3.82	5.01	3.56
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	-1.94	9.69	5.83	16.29	10.04	6.92	9.68
	SD	2.10	5.47	5.55	7.23	5.98	2.68	3.00
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	-1 61	8 05	4 29	13 15	10 98	4 97	6 24
	SD	2 33	4 25	2 98	6 03	4 85	4 28	1 40
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	0.10	9.70	9.50	20.79	17.05	8.15	9.94
	SD	1.86	6.04	5.44	6.86	7.25	4.69	3.49
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	-4.53	9.18	3.60	14.78	10.34	9.29	14.13
	SD	1.76	3.72	2.76	7.38	6.39	4.90	8.65
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
Group 6:	Mean	-3.33	6.16	1.49	7.17	12.56	15.42	18.41
30 µg/	SD	4.18	4.77	4.56	4.28	9.66	4.01	6.20
animal	N	15	15	15	5	5	5	5
BNT162c1		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 7:	Mean	-5.69	4.71	1.24	9.33	6.35	5.50	8.39
100 µg/	SD	2.59	2.91	2.99	3.95	3.85	1.76	4.16
animal	N	15	15	15	15	15	5	5
BNT162b2		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 1: Control	Mean	8.60	11.89	13.91	18.28	17.10
	SD	3.84	3.96	4.64	3.49	5.13
	N	5	5	5	5	5
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	13.04	17.60	19.64	22.48	23.62
	SD	4.97	3.93	5.99	4.58	6.47
	N	5	5	5	5	5
		-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	8 49	13 76	14 00	15 28	15 77
	SD	1 12	2 54	2 81	2 36	1 50
	N	5	5	5	5	5
		-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	10.60	15.71	16.49	19.29	17.35
	SD	3.14	2.80	2.31	2.31	2.36
	N	5	5	5	5	5
		-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	20.92	21.76	21.04	24.59	24.62
	SD	10.19	5.26	5.58	3.52	3.78
	N	5	5	5	5	5
		-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date	
		9 → 29	9 → 30
Group 6:	Mean	23.79	21.15
30 µg/	SD	5.84	6.53
animal	N	5	5
BNT162c1		-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 7:	Mean	12.31	17.04	18.70	21.33	17.79
100 µg/	SD	3.99	4.14	4.41	4.12	4.74
animal	N	5	5	5	5	5
BNT162b2		-	-	-	-	-

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
1	1.7	17.4	21.0	35.4	35.7	-	-
2	0.6	17.0	18.3	31.0	33.0	-	-
3	3.3	22.5	25.2	41.2	43.4	-	-
4	3.6	18.8	21.5	34.5	36.0	-	-
5	2.1	19.6	21.3	31.7	33.7	-	-
6	3.0	19.1	22.0	41.5	42.9	-	-
7	3.2	19.1	23.5	36.0	37.5	-	-
8	0.9	16.5	20.5	31.7	33.6	-	-
9	3.0	24.3	28.5	46.5	47.2	-	-
10	1.0	19.8	24.4	33.7	34.8	-	-
11	2.2	16.9	20.3	31.0	34.4	0.2	3.8
12	2.6	9.5	12.4	34.2	38.4	-0.2	6.0
13	-1.1	14.0	18.8	30.4	31.3	2.7	8.4
14	1.1	15.9	18.3	31.3	32.4	2.2	4.2
15	3.6	19.2	24.3	38.5	42.9	1.6	8.5
Mean	2.06	17.97	21.34	35.25	37.14	1.29	6.19
SD	1.33	3.46	3.76	4.75	4.80	1.26	2.26
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	5.8	13.4	14.4	15.3	16.7
12	5.3	12.6	17.5	20.4	22.4
13	10.5	16.5	18.1	21.3	21.2
14	8.9	15.6	19.0	18.9	19.9
15	8.4	14.6	16.4	20.8	21.5
Mean	7.78	14.52	17.09	19.35	20.35
SD	2.20	1.57	1.80	2.43	2.22
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
31	-4.6	5.6	-0.9	14.7	7.8	-	-
32	-10.2	13.3	5.1	17.4	13.8	-	-
33	-1.2	19.1	13.1	35.6	24.6	-	-
34	-4.9	10.9	4.4	15.7	11.6	-	-
35	-4.4	12.0	6.8	21.9	16.3	-	-
36	-4.5	13.9	9.7	22.0	18.4	-	-
37	-5.2	9.8	4.7	18.5	14.2	-	-
38	-2.8	14.9	5.6	21.2	16.2	-	-
39	-7.8	7.7	-1.0	3.8	0.4	-	-
40	-3.5	9.2	3.6	15.4	10.2	-	-
41	-3.2	12.9	10.8	22.5	17.6	2.7	8.4
42	-2.9	10.7	5.1	18.9	14.3	3.9	11.4
43	-2.5	14.3	12.0	26.8	20.8	9.3	17.5
44	-3.0	12.3	5.9	25.6	20.6	3.3	10.5
45	-3.9	17.0	9.8	28.8	20.1	3.1	13.6
Mean	-4.30	12.23	6.31	20.60	15.14	4.46	12.27
SD	2.23	3.49	4.18	7.32	6.02	2.72	3.47
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
31	-	-	-	-	-
32	-	-	-	-	-
33	-	-	-	-	-
34	-	-	-	-	-
35	-	-	-	-	-
36	-	-	-	-	-
37	-	-	-	-	-
38	-	-	-	-	-
39	-	-	-	-	-
40	-	-	-	-	-
41	13.0	24.0	25.7	29.0	29.3
42	16.8	27.4	28.0	34.0	34.3
43	23.3	31.9	34.8	42.2	46.4
44	18.6	28.1	32.3	33.9	35.2
45	18.3	30.4	31.9	36.6	38.2
Mean	18.00	28.37	30.54	35.16	36.68
SD	3.69	3.00	3.62	4.80	6.31
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
61	-4.0	7.1	3.4	15.8	10.4	-	-
62	-5.8	8.7	-0.3	14.2	12.0	-	-
63	1.3	9.1	5.0	15.9	11.6	-	-
64	-4.0	6.5	0.3	11.5	10.3	-	-
65	-2.7	13.5	7.8	23.3	21.1	-	-
66	-5.4	1.5	-2.1	8.3	2.4	-	-
67	-3.2	11.9	4.6	17.6	14.0	-	-
68	-6.6	6.6	-1.9	10.3	3.9	-	-
69	-2.9	6.9	2.6	17.0	13.6	-	-
70	-3.1	11.0	3.6	14.8	11.3	-	-
71	-2.5	12.9	7.0	20.9	14.1	3.8	11.0
72	-2.5	8.9	5.3	18.1	14.2	2.7	10.4
73	-1.6	8.9	1.7	13.2	9.3	5.7	11.5
74	-4.6	8.8	0.8	14.3	12.6	5.4	11.1
75	-5.1	11.8	6.3	20.5	17.3	6.6	10.2
Mean	-3.51	8.94	2.93	15.71	11.87	4.84	10.86
SD	1.94	3.06	3.14	4.06	4.61	1.57	0.53
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
61	-	-	-	-	-
62	-	-	-	-	-
63	-	-	-	-	-
64	-	-	-	-	-
65	-	-	-	-	-
66	-	-	-	-	-
67	-	-	-	-	-
68	-	-	-	-	-
69	-	-	-	-	-
70	-	-	-	-	-
71	16.6	21.3	23.6	29.8	30.5
72	14.1	17.0	16.8	20.3	20.3
73	18.5	20.5	22.6	23.2	25.5
74	16.4	20.9	21.7	24.6	25.3
75	18.8	21.8	22.5	26.7	26.3
Mean	16.87	20.31	21.47	24.91	25.56
SD	1.90	1.92	2.68	3.60	3.64
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
91	-1.1	16.5	16.1	29.5	27.3	-	-
92	-2.8	16.5	14.1	24.6	22.6	-	-
93	-2.0	18.2	15.0	29.3	24.6	-	-
94	-1.6	12.8	11.1	22.9	23.9	-	-
95	-4.3	13.0	13.7	27.3	23.9	-	-
96	-3.4	16.4	14.3	33.9	29.2	-	-
97	-2.9	15.0	11.3	29.0	24.3	-	-
98	-1.1	16.0	14.9	28.7	26.4	-	-
99	-1.5	16.4	15.2	30.9	27.7	-	-
100	-3.8	13.3	7.9	22.3	17.1	-	-
101	-3.3	14.0	12.4	21.4	19.5	3.3	11.4
102	-4.4	15.4	12.3	32.2	28.2	6.7	9.4
103	-1.1	19.2	19.1	35.4	35.2	6.1	12.6
104	-1.9	16.5	12.2	28.4	23.9	7.4	12.1
105	-3.8	16.3	14.7	30.6	24.8	6.8	15.0
Mean	-2.61	15.71	13.63	28.43	25.24	6.06	12.10
SD	1.19	1.83	2.60	4.14	4.20	1.59	2.03
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
91	-	-	-	-	-
92	-	-	-	-	-
93	-	-	-	-	-
94	-	-	-	-	-
95	-	-	-	-	-
96	-	-	-	-	-
97	-	-	-	-	-
98	-	-	-	-	-
99	-	-	-	-	-
100	-	-	-	-	-
101	10.9	15.8	14.3	19.4	21.9
102	15.0	19.3	21.7	20.3	22.0
103	22.0	29.6	35.6	40.8	40.7
104	15.0	20.8	24.6	27.5	29.5
105	19.2	29.4	32.2	36.2	33.2
Mean	16.43	22.97	25.68	28.83	29.45
SD	4.31	6.22	8.45	9.49	7.98
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
121	-9.7	1.3	-4.3	11.3	7.7	-	-
122	-10.5	0.8	-7.1	6.5	1.3	-	-
123	-8.3	7.4	2.3	18.3	12.4	-	-
124	-3.6	8.7	5.2	20.8	16.5	-	-
125	-7.2	1.7	-4.0	10.2	6.0	-	-
126	-8.9	3.1	-1.6	14.7	10.1	-	-
127	-10.8	5.5	-2.8	14.4	7.5	-	-
128	-10.9	4.8	-5.5	12.1	1.3	-	-
129	-8.9	3.9	-3.9	8.5	2.0	-	-
130	-8.6	6.6	-2.4	18.2	9.5	-	-
131	-10.9	2.0	-5.1	10.6	3.2	7.5	13.3
132	-7.4	4.0	-5.7	11.6	2.8	8.9	14.0
133	-8.6	1.7	-7.7	8.4	0.8	10.6	16.8
134	-8.7	4.5	-2.4	12.5	5.9	6.1	11.3
135	-10.0	2.4	-7.4	7.8	2.3	6.0	12.1
Mean	-8.87	3.88	-3.50	12.41	5.95	7.83	13.49
SD	1.89	2.37	3.52	4.18	4.68	1.97	2.11
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
121	-	-	-	-	-
122	-	-	-	-	-
123	-	-	-	-	-
124	-	-	-	-	-
125	-	-	-	-	-
126	-	-	-	-	-
127	-	-	-	-	-
128	-	-	-	-	-
129	-	-	-	-	-
130	-	-	-	-	-
131	22.7	25.6	29.1	27.4	30.1
132	22.9	24.1	32.2	34.0	33.6
133	22.9	29.0	30.6	33.1	32.8
134	17.7	22.7	22.5	26.9	26.1
135	16.9	24.4	22.5	23.4	25.1
Mean	20.63	25.14	27.38	28.95	29.55
SD	3.04	2.37	4.60	4.47	3.84
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
151	-4.1	4.5	-2.3	-	-	-	-
152	-5.1	3.2	-2.3	-	-	-	-
153	-6.4	0.7	-3.6	-	-	-	-
154	-1.6	9.8	3.4	-	-	-	-
155	-4.7	6.3	2.1	-	-	-	-
156	-2.6	6.0	-1.1	-	-	-	-
157	-4.8	6.9	1.3	-	-	-	-
158	-7.8	-1.6	-6.8	-	-	-	-
159	-1.4	8.4	5.5	-	-	-	-
160	-7.4	4.8	-4.0	-	-	-	-
161	-4.4	5.6	-1.9	11.1	19.8	23.3	24.0
162	-6.8	3.5	-3.4	9.2	11.1	17.2	24.5
163	-4.7	9.7	3.6	10.1	17.4	22.8	26.7
164	-7.5	3.3	-4.9	9.1	13.3	20.0	25.3
165	-2.5	12.1	2.8	10.6	16.8	26.8	31.9
Mean	-4.79	5.54	-0.77	10.03	15.69	22.03	26.48
SD	2.10	3.57	3.63	0.87	3.43	3.63	3.18
N	15	15	15	5	5	5	5

TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date	
	9 → 29	9 → 30
151	-	-
152	-	-
153	-	-
154	-	-
155	-	-
156	-	-
157	-	-
158	-	-
159	-	-
160	-	-
161	23.1	25.0
162	28.5	26.4
163	26.4	27.8
164	28.0	29.0
165	31.1	31.2
Mean	27.42	27.88
SD	2.94	2.36
N	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
181	-3.2	5.0	-1.7	9.8	4.5	-	-
182	-10.0	2.8	-6.4	9.0	1.0	-	-
183	-10.1	6.5	-2.6	13.8	6.3	-	-
184	-8.2	6.0	-1.9	14.1	6.6	-	-
185	-8.8	3.3	-6.7	11.5	3.6	-	-
186	-7.9	5.8	-6.6	11.5	5.4	-	-
187	-8.7	2.9	-8.1	6.6	-1.8	-	-
188	-7.3	5.4	-2.3	17.6	8.8	-	-
189	-8.7	2.4	-7.5	10.0	3.7	-	-
190	-8.2	6.1	-0.2	16.5	10.7	-	-
191	-5.9	3.4	-4.5	11.7	4.9	2.2	10.2
192	-6.2	2.9	-2.4	11.2	6.4	3.1	9.6
193	-4.0	4.5	-1.2	12.0	8.7	3.3	8.6
194	-7.0	2.2	-6.1	9.1	-0.4	8.4	17.7
195	-5.7	1.9	-2.9	11.0	4.0	6.4	14.0
Mean	-7.34	4.06	-4.07	11.69	4.82	4.69	12.02
SD	2.02	1.61	2.59	2.88	3.41	2.59	3.78
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
181	-	-	-	-	-
182	-	-	-	-	-
183	-	-	-	-	-
184	-	-	-	-	-
185	-	-	-	-	-
186	-	-	-	-	-
187	-	-	-	-	-
188	-	-	-	-	-
189	-	-	-	-	-
190	-	-	-	-	-
191	17.8	22.4	25.9	27.4	31.1
192	15.2	17.8	21.2	24.3	23.6
193	16.1	19.9	22.9	24.3	25.5
194	23.4	28.3	28.9	29.8	32.7
195	18.6	25.6	27.4	29.6	31.6
Mean	18.21	22.80	25.27	27.09	28.90
SD	3.18	4.24	3.17	2.73	4.10
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
16	4.7	13.6	12.0	21.9	22.6	-	-
17	3.5	18.2	24.0	22.3	21.7	-	-
18	2.4	6.3	10.6	18.1	18.3	-	-
19	0.5	7.1	8.4	17.9	14.8	-	-
20	-0.4	7.0	6.5	14.1	14.4	-	-
21	0.7	13.1	11.6	16.1	17.6	-	-
22	0.9	6.9	11.0	14.2	13.4	-	-
23	1.4	7.7	10.6	17.6	17.7	-	-
24	2.4	9.1	11.6	18.7	20.3	-	-
25	1.6	11.3	11.7	16.2	17.2	-	-
26	-0.9	3.6	4.0	10.8	9.6	1.7	9.2
27	3.7	8.0	15.3	21.0	14.4	11.1	12.7
28	0.7	13.1	15.1	19.5	22.0	-0.4	2.8
29	-3.1	8.5	12.9	16.5	12.7	7.6	8.0
30	1.7	4.2	9.6	20.1	13.8	9.5	7.4
Mean	1.32	9.19	11.67	17.66	16.70	5.88	8.00
SD	1.94	3.95	4.48	3.15	3.82	5.01	3.56
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
16	-	-	-	-	-
17	-	-	-	-	-
18	-	-	-	-	-
19	-	-	-	-	-
20	-	-	-	-	-
21	-	-	-	-	-
22	-	-	-	-	-
23	-	-	-	-	-
24	-	-	-	-	-
25	-	-	-	-	-
26	5.6	7.5	6.0	13.4	10.1
27	11.8	17.4	17.9	21.2	21.4
28	4.1	8.6	14.1	21.5	22.2
29	13.0	13.4	16.2	16.1	18.0
30	8.5	12.5	15.4	19.3	13.7
Mean	8.60	11.89	13.91	18.28	17.10
SD	3.84	3.96	4.64	3.49	5.13
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
46	-3.4	7.7	4.6	9.4	4.0	-	-
47	-4.8	9.4	7.3	11.2	8.3	-	-
48	-0.6	11.7	11.4	26.0	23.6	-	-
49	-1.8	8.0	0.1	14.7	6.7	-	-
50	-4.0	2.3	4.0	13.1	8.8	-	-
51	-3.6	13.8	1.4	13.5	5.7	-	-
52	-0.1	12.6	12.7	31.6	19.6	-	-
53	0.8	14.7	10.5	23.2	12.7	-	-
54	-4.3	7.7	2.5	9.2	4.8	-	-
55	-3.7	10.7	4.0	13.8	9.6	-	-
56	1.0	12.2	10.2	22.1	15.3	4.6	6.3
57	-1.9	9.7	7.6	17.6	10.8	9.3	10.5
58	0.1	8.0	3.0	13.0	5.8	8.8	14.3
59	0.8	20.3	14.5	21.1	12.9	8.4	8.3
60	-3.7	-3.5	-6.5	4.8	2.0	3.5	9.0
Mean	-1.94	9.69	5.83	16.29	10.04	6.92	9.68
SD	2.10	5.47	5.55	7.23	5.98	2.68	3.00
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
46	-	-	-	-	-
47	-	-	-	-	-
48	-	-	-	-	-
49	-	-	-	-	-
50	-	-	-	-	-
51	-	-	-	-	-
52	-	-	-	-	-
53	-	-	-	-	-
54	-	-	-	-	-
55	-	-	-	-	-
56	14.0	24.5	27.8	24.4	26.1
57	11.4	15.1	13.9	16.0	15.3
58	20.8	17.1	22.7	27.4	32.5
59	11.7	15.8	20.0	24.9	24.2
60	7.3	15.5	13.8	19.7	20.1
Mean	13.04	17.60	19.64	22.48	23.62
SD	4.97	3.93	5.99	4.58	6.47
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
76	-5.6	10.0	3.3	19.3	16.0	-	-
77	-2.4	6.0	2.0	7.8	3.6	-	-
78	-3.8	8.6	5.9	14.9	8.9	-	-
79	-1.9	7.0	4.2	15.1	12.9	-	-
80	-2.5	3.3	2.1	6.7	8.6	-	-
81	1.4	19.0	12.8	11.9	14.6	-	-
82	-3.8	11.8	7.3	11.7	11.6	-	-
83	1.0	11.0	5.3	12.2	11.0	-	-
84	0.6	9.3	4.9	17.2	15.1	-	-
85	2.4	9.2	3.1	13.3	10.8	-	-
86	-4.0	3.0	1.5	4.8	3.1	6.2	7.3
87	-3.0	8.2	3.7	29.7	21.9	11.7	4.4
88	-2.2	2.9	1.4	9.9	7.3	1.6	5.8
89	0.6	3.5	1.5	9.0	7.9	4.3	5.7
90	-1.0	8.0	5.4	13.7	11.5	1.0	7.9
Mean	-1.61	8.05	4.29	13.15	10.98	4.97	6.24
SD	2.33	4.25	2.98	6.03	4.85	4.28	1.40
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
76	-	-	-	-	-
77	-	-	-	-	-
78	-	-	-	-	-
79	-	-	-	-	-
80	-	-	-	-	-
81	-	-	-	-	-
82	-	-	-	-	-
83	-	-	-	-	-
84	-	-	-	-	-
85	-	-	-	-	-
86	10.0	13.7	14.1	17.0	17.4
87	7.0	11.0	13.9	11.5	13.6
88	9.0	15.6	9.5	15.8	16.3
89	8.2	16.9	15.4	14.8	15.0
90	8.3	11.5	17.0	17.3	16.6
Mean	8.49	13.76	14.00	15.28	15.77
SD	1.12	2.54	2.81	2.36	1.50
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
106	-1.2	10.1	8.3	29.0	24.8	-	-
107	0.2	9.4	7.2	12.1	10.2	-	-
108	-1.3	15.2	13.1	20.2	17.6	-	-
109	1.1	18.5	21.2	36.2	35.0	-	-
110	0.1	-0.4	4.0	15.7	16.0	-	-
111	2.6	10.6	11.8	17.1	16.3	-	-
112	-2.0	-0.6	9.5	14.4	13.7	-	-
113	-1.0	16.1	14.0	28.2	22.8	-	-
114	0.5	10.1	8.3	22.2	14.4	-	-
115	3.8	12.9	8.4	20.3	20.3	-	-
116	2.1	6.8	8.8	23.1	14.0	11.1	11.8
117	-0.7	7.0	4.2	15.9	12.9	7.4	10.3
118	0.9	18.6	18.0	27.4	22.8	0.5	5.9
119	-3.4	3.0	0.6	13.5	6.6	12.5	14.5
120	-0.2	7.9	5.1	16.7	8.4	9.2	7.2
Mean	0.10	9.70	9.50	20.79	17.05	8.15	9.94
SD	1.86	6.04	5.44	6.86	7.25	4.69	3.49
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
106	-	-	-	-	-
107	-	-	-	-	-
108	-	-	-	-	-
109	-	-	-	-	-
110	-	-	-	-	-
111	-	-	-	-	-
112	-	-	-	-	-
113	-	-	-	-	-
114	-	-	-	-	-
115	-	-	-	-	-
116	9.9	14.3	17.7	19.4	18.5
117	6.8	12.5	12.8	16.6	16.2
118	8.6	14.9	17.7	18.4	17.4
119	13.6	19.8	18.5	22.9	20.4
120	14.1	17.1	15.7	19.2	14.2
Mean	10.60	15.71	16.49	19.29	17.35
SD	3.14	2.80	2.31	2.31	2.36
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
136	-3.7	10.4	6.0	24.6	20.1	-	-
137	-5.1	13.4	6.1	16.6	10.4	-	-
138	-1.2	4.9	2.1	10.2	6.3	-	-
139	-5.1	7.4	5.6	11.0	13.2	-	-
140	-2.0	10.2	4.4	13.2	12.3	-	-
141	-6.1	6.1	2.2	5.7	-0.4	-	-
142	-4.4	11.7	3.2	15.0	10.4	-	-
143	-3.8	8.4	5.4	24.1	21.3	-	-
144	-7.8	15.6	7.7	29.6	18.4	-	-
145	-4.6	8.3	2.6	8.9	6.0	-	-
146	-2.4	13.7	2.8	11.9	7.1	15.4	26.8
147	-6.5	3.2	-1.1	8.1	5.7	4.8	7.6
148	-5.7	11.2	3.1	21.2	10.7	3.8	7.6
149	-4.1	9.6	6.2	17.0	12.9	10.7	19.4
150	-5.3	3.6	-2.4	4.6	0.8	11.8	9.2
Mean	-4.53	9.18	3.60	14.78	10.34	9.29	14.13
SD	1.76	3.72	2.76	7.38	6.39	4.90	8.65
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
136	-	-	-	-	-
137	-	-	-	-	-
138	-	-	-	-	-
139	-	-	-	-	-
140	-	-	-	-	-
141	-	-	-	-	-
142	-	-	-	-	-
143	-	-	-	-	-
144	-	-	-	-	-
145	-	-	-	-	-
146	35.9	28.0	28.4	29.1	28.7
147	10.1	15.0	12.8	19.4	19.3
148	16.7	18.5	20.3	25.2	23.2
149	26.3	25.7	22.4	23.6	24.0
150	15.6	21.6	21.3	25.7	27.8
Mean	20.92	21.76	21.04	24.59	24.62
SD	10.19	5.26	5.58	3.52	3.78
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
166	2.3	9.6	6.0	-	-	-	-
167	-5.9	6.7	2.5	-	-	-	-
168	-8.4	-0.8	-2.3	-	-	-	-
169	1.0	14.6	7.9	-	-	-	-
170	-2.9	3.2	1.1	-	-	-	-
171	4.3	-2.2	6.3	-	-	-	-
172	-2.1	6.2	-2.6	-	-	-	-
173	-7.3	-0.5	-9.1	-	-	-	-
174	-6.1	3.2	-1.2	-	-	-	-
175	-6.0	9.5	2.5	-	-	-	-
176	-1.1	9.7	1.4	7.2	12.5	16.9	23.6
177	1.6	8.2	3.3	12.1	26.3	18.8	23.4
178	-6.1	8.3	1.5	3.8	6.0	12.8	13.2
179	-9.2	5.7	-2.4	10.7	16.6	18.9	21.5
180	-4.1	10.9	7.5	2.1	1.4	9.8	10.4
Mean	-3.33	6.16	1.49	7.17	12.56	15.42	18.41
SD	4.18	4.77	4.56	4.28	9.66	4.01	6.20
N	15	15	15	5	5	5	5

TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date	
	9 → 29	9 → 30
166	-	-
167	-	-
168	-	-
169	-	-
170	-	-
171	-	-
172	-	-
173	-	-
174	-	-
175	-	-
176	27.8	25.6
177	24.7	24.6
178	21.3	15.7
179	30.0	27.2
180	15.1	12.6
Mean	23.79	21.15
SD	5.84	6.53
N	5	5

TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
196	-3.9	2.7	2.1	12.6	12.0	-	-
197	-2.0	10.3	4.2	5.9	8.2	-	-
198	-4.7	10.5	5.6	13.8	9.5	-	-
199	-12.1	3.1	-3.8	11.8	2.6	-	-
200	-7.2	0.9	-1.9	4.0	0.5	-	-
201	-7.5	6.8	2.8	15.5	5.7	-	-
202	-5.5	6.6	0.7	2.4	3.4	-	-
203	-7.7	3.3	0.6	7.9	4.7	-	-
204	-3.6	5.9	6.9	4.6	8.3	-	-
205	-6.5	3.1	0.3	7.7	1.7	-	-
206	-6.7	2.2	-2.4	11.3	4.5	6.2	8.6
207	-5.9	1.6	-1.4	8.4	7.1	6.3	7.3
208	-1.4	3.6	3.2	12.4	14.8	2.4	1.9
209	-4.9	5.7	1.8	8.5	6.7	6.4	11.8
210	-5.8	4.3	-0.1	12.9	5.5	6.1	12.2
Mean	-5.69	4.71	1.24	9.33	6.35	5.50	8.39
SD	2.59	2.91	2.99	3.95	3.85	1.76	4.16
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
196	-	-	-	-	-
197	-	-	-	-	-
198	-	-	-	-	-
199	-	-	-	-	-
200	-	-	-	-	-
201	-	-	-	-	-
202	-	-	-	-	-
203	-	-	-	-	-
204	-	-	-	-	-
205	-	-	-	-	-
206	13.1	17.5	20.7	21.0	16.4
207	11.2	16.5	17.8	20.3	18.6
208	6.1	10.4	11.4	15.1	10.5
209	14.6	20.1	21.9	25.3	20.5
210	16.5	20.8	21.8	24.9	22.9
Mean	12.31	17.04	18.70	21.33	17.79
SD	3.99	4.14	4.41	4.12	4.74
N	5	5	5	5	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 1: Control	Day(s) Relative to Start Date			
	10	17	31	38
1	-	313.8	-	-
2	-	307.2	-	-
3	-	335.8	-	-
4	-	333.3	-	-
5	-	310.4	-	-
6	-	333.0	-	-
7	-	318.0	-	-
8	-	335.2	-	-
9	-	340.4	-	-
10	-	338.5	-	-
11	-	-	-	382.3
12	-	-	-	388.0
13	-	-	-	407.3
14	-	-	-	357.4
15	-	-	-	406.3
Mean	-	326.56	-	388.26
SD	-	12.71	-	20.47
N	-	10	-	5

TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
31	-	270.6	-	-
32	-	257.9	-	-
33	-	299.9	-	-
34	-	281.6	-	-
35	-	280.0	-	-
36	-	267.5	-	-
37	-	272.7	-	-
38	-	281.9	-	-
39	-	236.4	-	-
40	-	270.3	-	-
41	-	-	-	355.1
42	-	-	-	355.8
43	-	-	-	417.0
44	-	-	-	377.4
45	-	-	-	378.2
Mean	-	271.88	-	376.70
SD	-	16.75	-	25.15
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
61	-	350.3	-	-
62	-	302.2	-	-
63	-	344.3	-	-
64	-	323.3	-	-
65	-	336.8	-	-
66	-	320.4	-	-
67	-	355.1	-	-
68	-	277.7	-	-
69	-	313.5	-	-
70	-	354.3	-	-
71	-	-	-	410.7
72	-	-	-	376.6
73	-	-	-	366.9
74	-	-	-	422.0
75	-	-	-	442.8
Mean	-	327.79	-	403.80
SD	-	25.28	-	31.63
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
91	-	307.3	-	-
92	-	290.0	-	-
93	-	299.9	-	-
94	-	289.3	-	-
95	-	302.5	-	-
96	-	331.1	-	-
97	-	301.6	-	-
98	-	287.8	-	-
99	-	320.2	-	-
100	-	297.9	-	-
101	-	-	-	359.7
102	-	-	-	373.6
103	-	-	-	451.4
104	-	-	-	387.1
105	-	-	-	405.8
Mean	-	302.76	-	395.52
SD	-	13.86	-	35.58
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
121	-	331.9	-	-
122	-	272.1	-	-
123	-	306.9	-	-
124	-	363.7	-	-
125	-	289.6	-	-
126	-	340.9	-	-
127	-	303.9	-	-
128	-	277.5	-	-
129	-	301.0	-	-
130	-	301.1	-	-
131	-	-	-	420.9
132	-	-	-	374.8
133	-	-	-	361.8
134	-	-	-	402.4
135	-	-	-	376.2
Mean	-	308.86	-	387.22
SD	-	28.72	-	23.91
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	10	17	31	38
151	261.1	-	-	-
152	303.3	-	-	-
153	250.9	-	-	-
154	276.8	-	-	-
155	282.0	-	-	-
156	265.4	-	-	-
157	296.3	-	-	-
158	245.8	-	-	-
159	279.9	-	-	-
160	253.9	-	-	-
161	-	-	374.8	-
162	-	-	327.9	-
163	-	-	391.8	-
164	-	-	349.7	-
165	-	-	388.2	-
Mean	271.54	-	366.48	-
SD	19.37	-	27.17	-
N	10	-	5	-

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date			
	10	17	31	38
181	-	329.3	-	-
182	-	271.5	-	-
183	-	294.8	-	-
184	-	292.7	-	-
185	-	337.6	-	-
186	-	263.2	-	-
187	-	300.6	-	-
188	-	305.9	-	-
189	-	293.2	-	-
190	-	300.8	-	-
191	-	-	-	356.9
192	-	-	-	389.1
193	-	-	-	410.6
194	-	-	-	336.7
195	-	-	-	391.4
Mean	-	298.96	-	376.94
SD	-	22.58	-	29.63
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 1: Control	Day(s) Relative to Start Date			
	10	17	31	38
16	-	233.2	-	-
17	-	218.5	-	-
18	-	203.8	-	-
19	-	216.8	-	-
20	-	225.5	-	-
21	-	216.0	-	-
22	-	207.2	-	-
23	-	217.6	-	-
24	-	237.1	-	-
25	-	229.6	-	-
26	-	-	-	243.0
27	-	-	-	275.4
28	-	-	-	292.6
29	-	-	-	252.4
30	-	-	-	254.0
Mean	-	220.53	-	263.48
SD	-	10.78	-	20.14
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
46	-	212.9	-	-
47	-	215.9	-	-
48	-	220.2	-	-
49	-	206.1	-	-
50	-	213.3	-	-
51	-	193.3	-	-
52	-	207.1	-	-
53	-	198.6	-	-
54	-	207.6	-	-
55	-	209.4	-	-
56	-	-	-	248.5
57	-	-	-	246.3
58	-	-	-	275.8
59	-	-	-	262.4
60	-	-	-	249.6
Mean	-	208.44	-	256.52
SD	-	7.97	-	12.48
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
76	-	214.4	-	-
77	-	214.7	-	-
78	-	204.5	-	-
79	-	246.9	-	-
80	-	190.0	-	-
81	-	213.4	-	-
82	-	253.3	-	-
83	-	207.4	-	-
84	-	213.9	-	-
85	-	211.6	-	-
86	-	-	-	238.4
87	-	-	-	262.7
88	-	-	-	284.0
89	-	-	-	246.9
90	-	-	-	229.9
Mean	-	217.01	-	252.38
SD	-	19.01	-	21.43
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
106	-	233.3	-	-
107	-	231.4	-	-
108	-	216.4	-	-
109	-	261.4	-	-
110	-	232.2	-	-
111	-	248.3	-	-
112	-	210.9	-	-
113	-	245.2	-	-
114	-	212.2	-	-
115	-	219.8	-	-
116	-	-	-	256.8
117	-	-	-	253.4
118	-	-	-	273.4
119	-	-	-	258.8
120	-	-	-	249.6
Mean	-	231.11	-	258.40
SD	-	16.76	-	9.09
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
136	-	245.4	-	-
137	-	212.3	-	-
138	-	254.9	-	-
139	-	226.8	-	-
140	-	209.9	-	-
141	-	240.7	-	-
142	-	205.9	-	-
143	-	227.9	-	-
144	-	243.8	-	-
145	-	240.9	-	-
146	-	-	-	238.8
147	-	-	-	251.1
148	-	-	-	243.2
149	-	-	-	278.6
150	-	-	-	257.9
Mean	-	230.85	-	253.92
SD	-	16.95	-	15.62
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	10	17	31	38
166	192.1	-	-	-
167	201.7	-	-	-
168	174.9	-	-	-
169	196.4	-	-	-
170	225.0	-	-	-
171	192.7	-	-	-
172	190.2	-	-	-
173	183.2	-	-	-
174	187.6	-	-	-
175	204.0	-	-	-
176	-	-	221.1	-
177	-	-	235.9	-
178	-	-	224.7	-
179	-	-	233.5	-
180	-	-	285.9	-
Mean	194.78	-	240.22	-
SD	13.59	-	26.25	-
N	10	-	5	-

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date			
	10	17	31	38
196	-	248.5	-	-
197	-	205.9	-	-
198	-	200.7	-	-
199	-	195.0	-	-
200	-	248.7	-	-
201	-	211.3	-	-
202	-	203.1	-	-
203	-	225.1	-	-
204	-	234.5	-	-
205	-	213.1	-	-
206	-	-	-	236.3
207	-	-	-	247.4
208	-	-	-	238.7
209	-	-	-	241.1
210	-	-	-	261.7
Mean	-	218.59	-	245.04
SD	-	19.60	-	10.19
N	-	10	-	5

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Male		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 1:	Mean	95.02	89.37	79.37	74.29	71.17
Control	SD	4.58	3.07	3.18	2.75	4.85
	N	15	15	5	5	5
		-	-	-	-	-
Group 2:	Mean	89.60*	82.93**	78.47	85.90**	78.78**
30 µg/	SD	5.50	4.86	3.15	3.32	2.09
animal	N	15	15	5	5	5
BNT162a1	%Diff	-5.7	-7.2	-1.1	15.6	10.7
Group 3:	Mean	78 93**	80 15**	70 54**	69 89	70 18
10 µg/	SD	4 99	5 23	4 92	4 87	3 36
animal	N	15	15	5	5	5
BNT162a1	%Diff	-16.9	-10.3	-11.1	-5.9	-1.4
Group 4:	Mean	90.88	87.19	74.95	76.22	70.46
30 µg/	SD	5.24	4.51	2.05	4.45	3.44
animal	N	15	15	5	5	5
BNT162b1	%Diff	-4.4	-2.4	-5.6	2.6	-1.0

Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Male		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 5:	Mean	73.25**	78.44**	69.61**	74.13	70.34
100 µg/	SD	5.22	4.70	3.06	7.97	1.75
animal	N	15	15	5	5	5
BNT162b1	%Diff	-22.9	-12.2	-12.3	-0.2	-1.2
Group 6:	Mean	77.41**	77.14**	74.10	72.39	-
30 µg/	SD	2.78	2.41	3.86	5.35	-
animal	N	15	5	5	5	-
BNT162c1	%Diff	-18.5	-13.7	-6.6	-2.6	-
Group 7:	Mean	73 79**	79 48**	68 70**	78 21	71 79
100 µg/	SD	5 13	6 12	3 17	5 55	3 43
animal	N	15	15	5	5	5
BNT162b2	%Diff	-22.3	-11.1	-13.4	5.3	0.9

Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Female		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 1:	Mean	98.30	94.31	82.23	85.56	81.65
Control	SD	6.46	5.55	5.07	6.08	5.64
	N	15	15	5	5	5
		-	-	-	-	-
Group 2:	Mean	95.08	90.19	83.01	88.56	85.17
30 µg/	SD	6.23	7.02	5.39	5.41	2.09
animal	N	15	15	5	5	5
BNT162a1	%Diff	-3.3	-4.4	0.9	3.5	4.3
Group 3:	Mean	91 92*	93 16	85 45	88 77	81 33
10 µg/	SD	6 28	6 42	9 00	6 33	5 85
animal	N	15	15	5	5	5
BNT162a1	%Diff	-6.5	-1.2	3.9	3.8	-0.4
Group 4:	Mean	96.59	93.89	81.64	84.09	79.63
30 µg/	SD	6.84	6.67	6.27	3.65	3.75
animal	N	15	15	5	5	5
BNT162b1	%Diff	-1.7	-0.4	-0.7	-1.7	-2.5

Anova & Dunnett: * = $p \leq 0.05$

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Female		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 5:	Mean	85.20**	92.31	86.22	96.32*	80.15
100 µg/	SD	7.16	5.32	4.66	6.53	6.97
animal	N	15	15	5	5	5
BNT162b1	%Diff	-13.3	-2.1	4.9	12.6	-1.8
Group 6:	Mean	88.75**	91.99	88.83	88.76	-
30 µg/	SD	5.68	5.49	7.46	3.90	-
animal	N	15	5	5	5	-
BNT162c1	%Diff	-9.7	-2.5	8.0	3.7	-
Group 7:	Mean	84 82**	92 22	85 38	96 84**	85 75
100 µg/	SD	5 22	5 49	4 86	1 80	3 65
animal	N	15	15	5	5	5
BNT162b2	%Diff	-13.7	-2.2	3.8	13.2	5.0

Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 4-1 Food Consumption - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Relative Food Consumption	2	Male	TW 1	*	Anova & Dunnett: * = p ≤ 0.05
	Relative Food Consumption	2	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	2	Male	TW 4	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	2	Male	TW 5	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	3	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	3	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	3	Male	TW 3	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Male	TW 3	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	6	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	6	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Male	TW 3	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 4-1 Food Consumption - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Relative Food Consumption	3	Female	TW 1	*	Anova & Dunnett: * = p ≤ 0.05
	Relative Food Consumption	5	Female	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Female	TW 4	*	Anova & Dunnett: * = p ≤ 0.05
	Relative Food Consumption	6	Female	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Female	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Female	TW 4	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 1: Control	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
1	95.1	89.9	-	-	-
2	97.3	92.4	-	-	-
3	97.6	88.0	-	-	-
4	88.9	87.0	-	-	-
5	99.6	90.9	-	-	-
6	105.0	96.5	-	-	-
7	94.3	84.9	-	-	-
8	88.0	86.9	-	-	-
9	97.1	93.0	-	-	-
10	96.4	88.7	-	-	-
11	96.5	87.6	75.7	70.8	72.6
12	94.2	91.8	82.0	77.8	75.7
13	88.3	85.9	76.1	72.9	62.9
14	96.2	88.5	81.7	73.8	72.4
15	90.9	88.7	81.3	76.1	72.4
Mean	95.02	89.37	79.37	74.29	71.17
SD	4.58	3.07	3.18	2.75	4.85
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
31	80.5	80.3	-	-	-
32	92.0	79.7	-	-	-
33	94.8	84.2	-	-	-
34	84.9	77.1	-	-	-
35	97.7	88.0	-	-	-
36	87.7	84.6	-	-	-
37	83.8	82.3	-	-	-
38	88.1	82.1	-	-	-
39	87.4	72.5	-	-	-
40	86.3	81.5	-	-	-
41	99.6	93.6	81.1	86.1	79.7
42	94.6	86.2	80.1	85.6	81.4
43	93.7	83.1	80.3	85.5	77.3
44	88.1	86.4	77.3	90.8	79.3
45	84.8	82.4	73.4	81.5	76.1
Mean	89.60	82.93	78.47	85.90	78.78
SD	5.50	4.86	3.15	3.32	2.09
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
61	75.0	73.5	-	-	-
62	74.6	82.6	-	-	-
63	75.9	75.1	-	-	-
64	75.1	79.5	-	-	-
65	87.4	87.5	-	-	-
66	77.1	78.2	-	-	-
67	76.8	78.3	-	-	-
68	74.6	73.1	-	-	-
69	84.5	87.9	-	-	-
70	76.3	77.2	-	-	-
71	82.8	83.3	66.8	67.3	71.8
72	88.9	84.9	70.5	76.9	68.7
73	81.6	86.9	77.9	64.1	75.3
74	73.3	73.3	65.4	72.0	67.2
75	79.7	81.1	72.1	69.1	67.9
Mean	78.93	80.15	70.54	69.89	70.18
SD	4.99	5.23	4.92	4.87	3.36
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
91	93.4	88.5	-	-	-
92	89.5	84.9	-	-	-
93	91.3	89.5	-	-	-
94	101.3	95.6	-	-	-
95	93.2	87.0	-	-	-
96	87.4	84.5	-	-	-
97	85.2	82.4	-	-	-
98	100.2	93.4	-	-	-
99	85.0	85.6	-	-	-
100	87.7	86.5	-	-	-
101	91.6	89.6	75.9	79.3	71.8
102	96.0	92.8	77.1	76.4	68.2
103	89.3	83.3	75.1	77.7	74.2
104	83.8	78.5	71.6	68.5	65.7
105	88.2	85.8	75.0	79.1	72.4
Mean	90.88	87.19	74.95	76.22	70.46
SD	5.24	4.51	2.05	4.45	3.44
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
121	66.5	72.3	-	-	-
122	67.7	75.8	-	-	-
123	71.9	81.1	-	-	-
124	78.3	74.9	-	-	-
125	76.1	83.5	-	-	-
126	75.7	82.0	-	-	-
127	74.9	86.9	-	-	-
128	73.3	81.5	-	-	-
129	72.0	71.0	-	-	-
130	76.9	79.3	-	-	-
131	68.4	71.4	67.2	64.6	68.9
132	85.7	81.9	68.7	84.3	71.7
133	71.7	80.5	75.0	73.2	72.6
134	74.4	78.1	68.8	68.8	68.5
135	65.2	76.4	68.3	79.7	69.9
Mean	73.25	78.44	69.61	74.13	70.34
SD	5.22	4.70	3.06	7.97	1.75
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
151	77.2	-	-	-	-
152	77.5	-	-	-	-
153	72.7	-	-	-	-
154	81.1	-	-	-	-
155	81.5	-	-	-	-
156	77.3	-	-	-	-
157	73.4	-	-	-	-
158	78.1	-	-	-	-
159	81.8	-	-	-	-
160	78.7	-	-	-	-
161	79.4	80.0	78.0	64.5	-
162	76.6	76.3	68.4	69.7	-
163	74.6	73.5	72.2	73.6	-
164	75.4	77.9	75.3	76.9	-
165	76.1	77.9	76.7	77.2	-
Mean	77.41	77.14	74.10	72.39	-
SD	2.78	2.41	3.86	5.35	-
N	15	5	5	5	-

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
181	63.1	70.9	-	-	-
182	68.6	77.0	-	-	-
183	76.3	76.0	-	-	-
184	79.3	87.4	-	-	-
185	69.6	74.3	-	-	-
186	80.1	90.9	-	-	-
187	67.1	71.1	-	-	-
188	79.6	85.1	-	-	-
189	73.0	78.4	-	-	-
190	78.9	86.7	-	-	-
191	75.1	81.7	66.6	82.7	72.3
192	72.1	77.2	66.8	75.7	66.2
193	78.3	83.0	72.7	83.7	73.5
194	72.5	73.4	65.8	78.9	71.5
195	73.1	79.1	71.5	70.1	75.4
Mean	73.79	79.48	68.70	78.21	71.79
SD	5.13	6.12	3.17	5.55	3.43
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 1: Control	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
16	105.2	98.1	-	-	-
17	107.6	98.6	-	-	-
18	105.2	92.7	-	-	-
19	91.1	89.2	-	-	-
20	94.4	91.8	-	-	-
21	98.2	86.9	-	-	-
22	111.5	107.9	-	-	-
23	93.3	91.7	-	-	-
24	97.9	90.4	-	-	-
25	95.2	87.1	-	-	-
26	90.8	98.7	84.4	91.6	89.2
27	96.1	92.5	78.6	77.8	75.2
28	95.7	93.8	87.5	80.4	84.0
29	91.3	96.5	85.3	89.3	77.0
30	101.0	98.8	75.3	88.8	82.8
Mean	98.30	94.31	82.23	85.56	81.65
SD	6.46	5.55	5.07	6.08	5.64
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
46	101.4	82.9	-	-	-
47	93.6	96.2	-	-	-
48	100.1	100.9	-	-	-
49	82.6	79.0	-	-	-
50	97.5	86.0	-	-	-
51	82.9	86.9	-	-	-
52	97.9	95.8	-	-	-
53	99.4	86.7	-	-	-
54	97.8	96.4	-	-	-
55	96.0	94.4	-	-	-
56	89.4	87.2	79.6	86.1	85.3
57	101.9	102.5	89.2	97.4	87.0
58	89.4	82.7	84.8	83.0	82.1
59	97.4	87.5	75.6	87.2	84.4
60	98.8	87.6	85.8	89.0	87.2
Mean	95.08	90.19	83.01	88.56	85.17
SD	6.23	7.02	5.39	5.41	2.09
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
76	88.1	105.6	-	-	-
77	86.6	89.2	-	-	-
78	99.4	98.0	-	-	-
79	94.8	96.9	-	-	-
80	87.0	94.3	-	-	-
81	99.0	83.8	-	-	-
82	82.3	90.2	-	-	-
83	88.7	90.9	-	-	-
84	95.0	97.6	-	-	-
85	91.5	91.6	-	-	-
86	89.8	86.7	77.9	88.0	77.9
87	97.4	101.9	95.9	82.6	78.1
88	81.2	82.1	74.6	85.1	75.6
89	96.7	95.0	91.4	99.2	89.1
90	101.2	93.6	87.6	89.0	86.0
Mean	91.92	93.16	85.45	88.77	81.33
SD	6.28	6.42	9.00	6.33	5.85
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
106	89.8	90.1	-	-	-
107	91.9	89.8	-	-	-
108	99.4	100.2	-	-	-
109	91.7	100.5	-	-	-
110	85.3	88.2	-	-	-
111	94.3	99.2	-	-	-
112	112.1	101.3	-	-	-
113	99.0	100.6	-	-	-
114	105.1	103.5	-	-	-
115	90.6	85.0	-	-	-
116	103.7	83.3	80.2	84.2	77.4
117	95.1	93.6	81.4	82.7	77.2
118	97.1	89.3	73.6	78.7	77.7
119	99.4	96.0	91.2	87.3	86.1
120	94.2	87.8	81.8	87.5	79.7
Mean	96.59	93.89	81.64	84.09	79.63
SD	6.84	6.67	6.27	3.65	3.75
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
136	83.3	92.8	-	-	-
137	88.0	93.2	-	-	-
138	94.4	100.8	-	-	-
139	88.9	95.9	-	-	-
140	78.6	91.5	-	-	-
141	77.8	89.0	-	-	-
142	99.6	95.5	-	-	-
143	90.9	96.0	-	-	-
144	89.9	101.8	-	-	-
145	73.8	80.6	-	-	-
146	86.3	89.9	91.4	84.8	78.1
147	85.1	90.9	88.7	98.8	83.4
148	85.4	89.0	79.0	99.8	86.0
149	80.3	90.2	84.9	97.7	68.9
150	75.7	87.4	87.1	100.5	84.4
Mean	85.20	92.31	86.22	96.32	80.15
SD	7.16	5.32	4.66	6.53	6.97
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
166	92.5	-	-	-	-
167	89.9	-	-	-	-
168	99.2	-	-	-	-
169	87.8	-	-	-	-
170	76.9	-	-	-	-
171	84.3	-	-	-	-
172	85.5	-	-	-	-
173	89.0	-	-	-	-
174	86.2	-	-	-	-
175	87.4	-	-	-	-
176	83.9	88.4	78.0	90.0	-
177	95.5	92.2	95.0	84.6	-
178	95.4	100.9	94.6	94.3	-
179	84.9	91.7	92.4	89.4	-
180	92.9	86.7	84.2	85.5	-
Mean	88.75	91.99	88.83	88.76	-
SD	5.68	5.49	7.46	3.90	-
N	15	5	5	5	-

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
196	72.8	85.2	-	-	-
197	88.1	101.2	-	-	-
198	83.7	100.5	-	-	-
199	86.8	94.3	-	-	-
200	76.7	85.5	-	-	-
201	90.0	93.3	-	-	-
202	86.3	90.3	-	-	-
203	84.2	94.9	-	-	-
204	86.6	98.2	-	-	-
205	79.9	83.8	-	-	-
206	83.7	93.3	88.4	100.0	87.8
207	82.6	87.8	83.1	95.6	84.0
208	91.1	93.7	90.2	96.7	81.6
209	89.6	94.2	87.1	95.8	90.9
210	90.4	87.0	78.1	96.2	84.5
Mean	84.82	92.22	85.38	96.84	85.75
SD	5.22	5.49	4.86	1.80	3.65
N	15	15	5	5	5

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date						
		1 (4 h pa) [a]	2 (24h pa) [a]	8 (4 h pa) [a1]	9 (24h pa) [a]	15 [a2]	15 (4 h pa) [a2]	16 (24h pa) [a2]
Group 1:	Mean	37.36	37.51	37.26	37.31	-	38.25	38.04
Control	SD	0.21	0.37	0.25	0.56	-	0.29	0.38
	N	15	15	15	15	-	15	15
		-	-	-	-	-	-	-
Group 2:	Mean	37.92**	38.54**	37.91**	39.03**	-	38.23	38.91**
30 µg/	SD	0.38	0.27	0.49	0.37	-	0.35	0.46
animal	N	15	15	15	15	-	15	15
BNT162a1	%Diff	1.5	2.8	1.7	4.6	-	0.0	2.3
Group 3:	Mean	37 69*	36 98	37 59	38 05	-	37 62**	38 18
10 µg/	SD	0 30	0 69	0 36	0 33	-	0 56	0 43
animal	N	15	15	15	15	-	15	15
BNT162a1	%Diff	0.9	-1.4	0.9	2.0	-	-1.6	0.4
Group 4:	Mean	37.57	37.76	37.46	38.19**	-	37.43**	37.97
30 µg/	SD	0.48	0.35	0.50	0.49	-	0.38	0.46
animal	N	15	15	15	15	-	15	15
BNT162b1	%Diff	0.6	0.7	0.5	2.4	-	-2.1	-0.2

[a] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a2] - Anova & Dunnett: ** = $p \leq 0.01$

TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date						
		1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15	15 (4 h pa)	16 (24h pa)
Group 5:	Mean	38.65**	36.70**	38.01**	38.97**	-	38.74*	39.09**
100 µg/	SD	0.58	0.71	0.43	0.36	-	0.58	0.40
animal	N	15	15	15	15	-	15	15
BNT162b1	%Diff	3.5	-2.2	2.0	4.5	-	1.3	2.8
Group 6:	Mean	38.27**	36.59**	37.98**	38.98**	38.60n	-	-
30 µg/	SD	0.32	0.87	0.27	0.20	0.23	-	-
animal	N	15	15	15	15	5	-	-
BNT162c1	%Diff	2.4	-2.5	1.9	4.5	-	-	-
Group 7:	Mean	38 49**	37 45	38 07**	38 94**	-	38 60	39 11**
100 µg/	SD	0 38	0 75	0 38	0 52	-	0 54	0 34
animal	N	15	15	15	15	-	15	15
BNT162b2	%Diff	3.0	-0.2	2.2	4.4	-	0.9	2.8

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date		
		22 [a]	29 [a]	36 [a1]
Group 1:	Mean	37.40	37.72	36.82
Control	SD	0.55	0.47	0.62
	N	5	5	5
	-	-	-	-
Group 2:	Mean	37.80	38.42	37.42
30 µg/	SD	0.59	0.23	0.68
animal	N	5	5	5
BNT162a1	%Diff	1.1	1.9	1.6
Group 3:	Mean	38 36*	38 58	37 62
10 µg/	SD	0 43	0 64	0 70
animal	N	5	5	5
BNT162a1	%Diff	2.6	2.3	2.2
Group 4:	Mean	38.40*	38.66*	38.24*
30 µg/	SD	0.55	0.54	0.85
animal	N	5	5	5
BNT162b1	%Diff	2.7	2.5	3.9

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank): * = p ≤ 0.05

TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date		
		22	29	36
Group 5:	Mean	38.38*	38.38	37.46
100 µg/	SD	0.49	0.68	0.86
animal	N	5	5	5
BNT162b1	%Diff	2.6	1.7	1.7
Group 6:	Mean	38.48**	39.00**	-
30 µg/	SD	0.34	0.36	-
animal	N	5	5	-
BNT162c1	%Diff	2.9	3.4	-
Group 7:	Mean	38 44*	38 68*	36 96
100 µg/	SD	0 38	0 44	0 39
animal	N	5	5	5
BNT162b2	%Diff	2.8	2.5	0.4

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date						
		1 (4 h pa) [a]	2 (24h pa) [a1]	3 (48h pa) [a]	8 (4 h pa) [a1]	9 (24h pa) [a1]	15 [a]	15 (4 h pa) [a]
Group 1:	Mean	37.37	38.25	-	37.64	38.43	-	38.87
Control	SD	0.30	0.67	-	0.54	0.78	-	0.30
	N	15	15	-	15	15	-	15
		-	-	-	-	-	-	-
Group 2:	Mean	38.30**	38.63	-	38.35**	39.05	-	38.65
30 µg/	SD	0.62	0.38	-	0.37	0.40	-	0.49
animal	N	15	15	-	15	15	-	15
BNT162a1	%Diff	2.5	1.0	-	1.9	1.6	-	-0.5
Group 3:	Mean	38 19**	38 38	-	37 95	38 79	-	38 91
10 µg/	SD	0 52	0 42	-	0 57	0 47	-	0 63
animal	N	15	15	-	15	15	-	15
BNT162a1	%Diff	2.2	0.3	-	0.8	0.9	-	0.1
Group 4:	Mean	37.73	38.47	-	38.15	38.66	-	37.63**
30 µg/	SD	0.53	0.63	-	0.81	0.58	-	0.55
animal	N	15	15	-	15	15	-	15
BNT162b1	%Diff	1.0	0.6	-	1.3	0.6	-	-3.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date						
		1 (4 h pa)	2 (24h pa)	3 (48h pa)	8 (4 h pa)	9 (24h pa)	15	15 (4 h pa)
Group 5:	Mean	38.41**	38.35	-	38.22*	38.99	-	39.17
100 µg/	SD	0.43	0.73	-	0.53	0.30	-	0.47
animal	N	15	15	-	15	15	-	15
BNT162b1	%Diff	2.8	0.2	-	1.5	1.4	-	0.8
Group 6:	Mean	38.69**	38.12	39.20n	38.44**	39.03	38.70n	-
30 µg/	SD	0.57	1.16	-	0.64	0.45	0.37	-
animal	N	15	15	1	15	15	5	-
BNT162c1	%Diff	3.6	-0.3	-	2.1	1.6	-	-
Group 7:	Mean	38 51**	39 09**	-	38 35**	39 29**	-	39 13
100 µg/	SD	0 44	0 27	-	0 28	0 38	-	0 43
animal	N	15	15	-	15	15	-	15
BNT162b2	%Diff	3.1	2.2	-	1.9	2.2	-	0.7

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date				
		16 (24h pa) [a]	17 [a]	22 [a]	29 [a1]	36 [a1]
Group 1:	Mean	39.01	-	38.84	38.32	38.26
Control	SD	0.41	-	0.71	0.83	1.07
	N	15	-	5	5	5
		-	-	-	-	-
Group 2:	Mean	39.20	-	39.04	38.90	38.76
30 µg/	SD	0.59	-	0.55	0.28	0.91
animal	N	15	-	5	5	5
BNT162a1	%Diff	0.5	-	0.5	1.5	1.3
Group 3:	Mean	39 13	-	39 04	39 06	38 76
10 µg/	SD	0 48	-	0 37	0 49	0 84
animal	N	15	-	5	5	5
BNT162a1	%Diff	0.3	-	0.5	1.9	1.3
Group 4:	Mean	39.04	-	38.92	38.84	38.74
30 µg/	SD	0.56	-	0.36	0.43	0.30
animal	N	15	-	5	5	5
BNT162b1	%Diff	0.1	-	0.2	1.4	1.3

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date				
		16 (24h pa)	17	22	29	36
Group 5:	Mean	39.43	38.50 n	39.04	39.28	39.06
100 µg/	SD	0.47	-	0.35	0.24	0.34
animal	N	15	1	5	5	5
BNT162b1	%Diff	1.1	-	0.5	2.5	2.1
Group 6:	Mean	-	-	38.90	39.08	-
30 µg/	SD	-	-	0.20	0.34	-
animal	N	-	-	5	5	-
BNT162c1	%Diff	-	-	0.2	2.0	-
Group 7:	Mean	39 51*	-	39 00	39 00	39 18
100 µg/	SD	0 38	-	0 31	0 25	0 15
animal	N	15	-	5	5	5
BNT162b2	%Diff	1.3	-	0.4	1.8	2.4

Anova & Dunnett: * = p ≤ 0.05; n - Inappropriate for statistics

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TABLE 5-1 Body Temperature - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Temperature	2	Male	1 (4 h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	2	Male	2 (24h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	2	Male	8 (4 h pa)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	Body Temperature	2	Male	9 (24h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	2	Male	16 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	3	Male	1 (4 h pa)	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Temperature	3	Male	15 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	4	Male	9 (24h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	4	Male	15 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	3	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	4	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	4	Male	29	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	4	Male	36	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Temperature	5	Male	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	2 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	15 (4 h pa)	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	5	Male	16 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	2 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	15	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	7	Male	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	16 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 5-1 Body Temperature - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Temperature	5	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	6	Male	22	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	29	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	7	Male	29	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 5-1 Body Temperature - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Temperature	2	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	2	Female	8 (4 h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	3	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	4	Female	15 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Female	8 (4 h pa)	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	6	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Female	3 (48h pa)	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	6	Female	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Female	15	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	7	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Female	2 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Female	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Female	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Female	17	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	7	Female	16 (24h pa)	*	Anova & Dunnett: * = p ≤ 0.05

TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
1	37.1	37.1	37.2	36.9	38.4	38.2	-
2	37.3	37.5	37.4	38.0	38.7	38.8	-
3	37.2	37.2	37.3	37.2	38.2	37.6	-
4	37.4	38.2	37.3	37.4	38.7	38.1	-
5	37.4	37.6	37.1	38.1	37.9	38.2	-
6	37.9	37.4	37.3	37.2	38.2	37.7	-
7	37.4	37.2	36.9	36.6	38.3	38.1	-
8	37.7	38.2	37.7	37.4	38.7	38.4	-
9	37.3	37.3	37.3	37.7	38.0	38.5	-
10	37.2	37.0	37.0	37.9	38.3	38.3	-
11	37.1	38.0	36.9	38.0	38.1	37.9	36.6
12	37.3	37.3	37.7	37.4	38.1	37.4	37.1
13	37.4	37.6	37.1	36.5	38.2	37.7	37.6
14	37.4	37.4	37.5	36.5	37.7	37.7	38.0
15	37.3	37.6	37.2	36.8	38.2	38.0	37.7
Mean	37.36	37.51	37.26	37.31	38.25	38.04	37.40
SD	0.21	0.37	0.25	0.56	0.29	0.38	0.55
N	15	15	15	15	15	15	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date	
	29	36
1	-	-
2	-	-
3	-	-
4	-	-
5	-	-
6	-	-
7	-	-
8	-	-
9	-	-
10	-	-
11	37.4	36.4
12	37.8	36.5
13	37.1	36.8
14	38.1	36.5
15	38.2	37.9
Mean	37.72	36.82
SD	0.47	0.62
N	5	5

TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
31	37.8	38.3	37.5	38.6	38.7	39.1	-
32	37.4	38.4	37.8	39.1	37.9	39.1	-
33	38.2	39.0	38.2	39.1	38.0	39.2	-
34	37.2	38.5	37.4	38.8	37.9	37.8	-
35	38.1	38.3	38.2	38.8	38.5	38.5	-
36	38.1	38.3	37.4	39.2	38.4	39.2	-
37	38.6	39.0	38.7	39.4	38.6	39.2	-
38	38.2	38.6	38.8	39.3	38.2	39.6	-
39	38.2	38.6	38.3	39.5	38.3	39.1	-
40	38.2	38.7	38.1	39.1	38.3	39.0	-
41	38.0	38.3	37.9	38.8	38.5	39.2	38.3
42	37.9	39.0	37.3	39.5	38.1	38.7	37.1
43	37.3	38.2	37.2	38.1	38.6	38.3	37.7
44	37.8	38.4	38.0	38.9	38.1	38.5	38.5
45	37.8	38.5	37.8	39.2	37.4	39.1	37.4
Mean	37.92	38.54	37.91	39.03	38.23	38.91	37.80
SD	0.38	0.27	0.49	0.37	0.35	0.46	0.59
N	15	15	15	15	15	15	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date	
	29	36
31	-	-
32	-	-
33	-	-
34	-	-
35	-	-
36	-	-
37	-	-
38	-	-
39	-	-
40	-	-
41	38.5	38.6
42	38.5	37.4
43	38.7	36.9
44	38.3	37.1
45	38.1	37.1
Mean	38.42	37.42
SD	0.23	0.68
N	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
61	37.7	37.7	37.2	37.8	36.8	38.1	-
62	38.0	36.4	37.7	37.9	37.4	38.4	-
63	37.7	36.1	37.4	37.8	37.0	38.2	-
64	37.6	38.1	37.7	38.6	37.7	38.8	-
65	37.6	38.0	37.3	38.1	37.3	37.8	-
66	37.2	37.3	37.0	37.8	37.4	38.4	-
67	37.4	36.4	37.5	37.7	38.4	37.7	-
68	38.4	36.9	38.4	38.9	38.7	38.2	-
69	37.4	36.3	37.3	38.0	38.0	38.2	-
70	37.4	36.5	37.3	38.0	37.3	38.7	-
71	37.6	37.8	37.6	38.0	37.2	38.7	38.0
72	37.9	36.6	37.9	38.1	37.7	38.5	38.2
73	37.7	36.2	38.0	38.2	38.5	38.0	39.1
74	38.0	37.0	37.8	37.7	37.3	37.2	38.2
75	37.7	37.4	37.8	38.1	37.6	37.8	38.3
Mean	37.69	36.98	37.59	38.05	37.62	38.18	38.36
SD	0.30	0.69	0.36	0.33	0.56	0.43	0.43
N	15	15	15	15	15	15	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date	
	29	36
61	-	-
62	-	-
63	-	-
64	-	-
65	-	-
66	-	-
67	-	-
68	-	-
69	-	-
70	-	-
71	38.7	37.3
72	39.2	38.7
73	38.8	37.9
74	37.5	36.9
75	38.7	37.3
Mean	38.58	37.62
SD	0.64	0.70
N	5	5

TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
91	38.3	38.5	37.8	38.5	37.9	37.2	-
92	37.4	37.6	37.7	38.3	37.3	38.0	-
93	37.3	38.5	37.0	38.0	37.3	38.0	-
94	36.7	37.7	36.5	38.3	37.0	37.9	-
95	37.4	37.7	37.4	39.0	38.2	37.6	-
96	37.7	37.7	37.2	37.4	36.9	38.0	-
97	38.6	37.9	37.4	38.2	37.5	38.2	-
98	37.8	37.6	37.8	38.5	37.4	38.2	-
99	36.9	37.4	37.3	38.4	37.4	38.2	-
100	37.6	37.8	37.5	38.1	37.4	37.9	-
101	37.7	37.7	38.8	39.0	37.7	39.0	39.3
102	37.7	37.2	37.5	37.2	37.0	37.1	38.3
103	37.4	37.8	37.6	38.1	38.0	38.3	38.4
104	37.2	37.5	37.3	37.8	37.1	37.8	37.8
105	37.8	37.8	37.1	38.1	37.3	38.2	38.2
Mean	37.57	37.76	37.46	38.19	37.43	37.97	38.40
SD	0.48	0.35	0.50	0.49	0.38	0.46	0.55
N	15	15	15	15	15	15	5

TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date	
	29	36
91	-	-
92	-	-
93	-	-
94	-	-
95	-	-
96	-	-
97	-	-
98	-	-
99	-	-
100	-	-
101	39.4	39.5
102	38.8	38.7
103	38.3	37.9
104	38.8	37.5
105	38.0	37.6
Mean	38.66	38.24
SD	0.54	0.85
N	5	5

TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
121	38.2	38.0	38.2	38.4	38.3	39.4	-
122	38.0	35.7	38.4	39.4	39.4	39.5	-
123	38.0	36.7	37.6	38.6	38.2	39.0	-
124	38.2	36.1	37.6	38.8	37.8	38.6	-
125	39.2	37.4	38.0	39.4	39.7	39.1	-
126	38.5	36.8	38.0	38.7	38.6	39.1	-
127	38.1	38.1	37.7	39.5	39.1	39.2	-
128	39.4	37.2	38.7	39.0	39.3	39.7	-
129	39.3	36.8	37.4	39.2	38.6	39.3	-
130	38.0	36.1	38.0	38.8	38.8	39.4	-
131	39.1	36.4	38.7	38.7	39.1	39.1	38.2
132	38.8	36.5	38.5	39.4	39.2	39.3	37.8
133	39.5	36.1	38.0	39.2	38.5	38.7	38.6
134	39.2	36.1	38.0	39.0	38.8	38.9	39.1
135	38.3	36.5	37.4	38.5	37.7	38.1	38.2
Mean	38.65	36.70	38.01	38.97	38.74	39.09	38.38
SD	0.58	0.71	0.43	0.36	0.58	0.40	0.49
N	15	15	15	15	15	15	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date	
	29	36
121	-	-
122	-	-
123	-	-
124	-	-
125	-	-
126	-	-
127	-	-
128	-	-
129	-	-
130	-	-
131	37.7	38.2
132	37.8	36.6
133	39.1	38.3
134	39.1	37.7
135	38.2	36.5
Mean	38.38	37.46
SD	0.68	0.86
N	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15	22	29
151	38.1	35.7	37.9	38.8	-	-	-
152	38.6	37.5	37.9	38.7	-	-	-
153	38.2	35.5	38.1	39.0	-	-	-
154	38.1	36.1	37.8	39.0	-	-	-
155	38.2	36.4	37.7	38.7	-	-	-
156	38.1	36.7	37.4	39.0	-	-	-
157	38.2	36.3	38.1	38.8	-	-	-
158	39.1	36.1	38.0	39.4	-	-	-
159	38.2	37.8	38.1	39.0	-	-	-
160	38.0	37.2	38.0	38.8	-	-	-
161	38.5	38.1	38.1	39.2	39.0	38.6	39.1
162	38.1	36.9	38.2	39.0	38.6	38.6	38.6
163	38.2	37.4	38.0	39.1	38.5	38.8	39.5
164	38.6	35.9	38.6	39.2	38.4	38.5	39.1
165	37.8	35.2	37.8	39.0	38.5	37.9	38.7
Mean	38.27	36.59	37.98	38.98	38.60	38.48	39.00
SD	0.32	0.87	0.27	0.20	0.23	0.34	0.36
N	15	15	15	15	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
181	38.2	38.7	38.1	39.2	38.5	38.6	-
182	39.1	37.2	39.0	39.4	39.3	39.1	-
183	38.6	37.7	38.1	39.4	37.8	39.4	-
184	38.6	37.3	38.1	39.0	38.5	39.1	-
185	38.8	37.6	38.3	38.1	38.6	38.4	-
186	38.9	36.1	38.6	39.6	39.5	39.5	-
187	38.2	38.3	37.7	39.1	37.8	38.9	-
188	38.5	37.1	38.1	38.1	39.0	39.4	-
189	37.6	38.3	37.4	38.8	38.4	39.2	-
190	38.4	37.8	38.0	38.5	39.0	38.9	-
191	38.6	37.2	38.0	38.4	38.3	39.0	38.0
192	38.4	36.0	37.7	39.1	38.4	39.2	38.6
193	38.1	37.3	37.8	38.5	37.8	39.3	39.0
194	38.4	38.0	38.2	39.7	39.1	39.7	38.3
195	38.9	37.1	38.0	39.2	39.0	38.9	38.3
Mean	38.49	37.45	38.07	38.94	38.60	39.11	38.44
SD	0.38	0.75	0.38	0.52	0.54	0.34	0.38
N	15	15	15	15	15	15	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date	
	29	36
181	-	-
182	-	-
183	-	-
184	-	-
185	-	-
186	-	-
187	-	-
188	-	-
189	-	-
190	-	-
191	38.1	36.6
192	39.3	36.5
193	38.8	37.4
194	38.5	37.1
195	38.7	37.2
Mean	38.68	36.96
SD	0.44	0.39
N	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
16	37.1	38.4	37.6	39.0	38.8	38.9	-
17	37.2	38.0	37.4	37.7	38.6	38.7	-
18	37.0	37.5	38.0	38.3	38.1	38.1	-
19	37.3	37.3	37.4	36.6	39.2	39.0	-
20	37.3	37.6	37.0	38.2	39.1	38.8	-
21	37.3	37.7	37.3	38.1	38.7	38.7	-
22	37.3	39.4	38.3	39.4	39.0	39.6	-
23	37.7	37.7	38.5	39.4	38.8	39.2	-
24	37.9	38.7	38.3	38.8	38.8	39.1	-
25	37.2	38.6	37.1	38.0	38.8	38.8	-
26	37.4	39.4	37.2	39.0	39.4	39.2	-
27	37.0	37.8	37.0	37.5	38.7	39.1	-
28	37.2	38.2	38.5	39.0	39.0	38.7	-
29	37.7	38.9	37.4	39.0	39.0	39.7	-
30	37.9	38.6	37.6	38.5	39.0	39.5	-
Mean	37.37	38.25	37.64	38.43	38.87	39.01	-
SD	0.30	0.67	0.54	0.78	0.30	0.41	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date		
	22	29	36
16	-	-	-
17	-	-	-
18	-	-	-
19	-	-	-
20	-	-	-
21	-	-	-
22	-	-	-
23	-	-	-
24	-	-	-
25	-	-	-
26	38.7	39.0	39.4
27	37.7	36.9	37.1
28	39.0	38.7	37.7
29	39.5	38.7	37.7
30	39.3	38.3	39.4
Mean	38.84	38.32	38.26
SD	0.71	0.83	1.07
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
46	38.8	38.5	38.2	39.0	38.4	38.9	-
47	38.4	38.3	37.7	38.7	39.0	39.7	-
48	37.8	38.5	38.1	38.5	38.0	38.3	-
49	37.4	38.8	38.0	39.2	37.7	39.2	-
50	37.2	38.1	38.3	38.8	38.5	39.1	-
51	38.2	38.6	38.8	39.2	39.0	39.4	-
52	38.9	38.6	38.0	39.1	38.2	38.7	-
53	37.7	38.7	38.6	39.8	38.7	40.2	-
54	38.5	38.6	38.7	38.7	39.6	39.9	-
55	39.4	39.6	38.9	39.7	39.4	39.9	-
56	38.5	38.2	38.4	38.8	38.6	38.9	-
57	38.6	39.1	38.5	39.2	38.5	39.8	-
58	38.6	38.8	38.9	39.6	38.8	39.0	-
59	38.8	38.8	38.2	38.7	38.7	38.5	-
60	37.7	38.2	38.0	38.7	38.7	38.5	-
Mean	38.30	38.63	38.35	39.05	38.65	39.20	-
SD	0.62	0.38	0.37	0.40	0.49	0.59	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date		
	22	29	36
46	-	-	-
47	-	-	-
48	-	-	-
49	-	-	-
50	-	-	-
51	-	-	-
52	-	-	-
53	-	-	-
54	-	-	-
55	-	-	-
56	39.5	39.0	39.7
57	39.1	38.6	39.2
58	39.4	38.6	37.3
59	39.1	39.1	39.0
60	38.1	39.2	38.6
Mean	39.04	38.90	38.76
SD	0.55	0.28	0.91
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
76	38.2	38.2	38.2	38.7	38.7	38.5	-
77	39.1	39.0	37.4	38.5	39.1	39.0	-
78	38.0	38.8	37.4	38.6	38.5	38.5	-
79	38.1	38.0	38.6	39.4	39.1	39.5	-
80	38.0	38.0	37.8	38.6	39.4	39.3	-
81	38.6	38.4	38.0	38.4	39.6	38.7	-
82	37.7	37.7	38.0	38.6	38.0	39.4	-
83	38.9	38.3	37.8	38.6	38.3	39.0	-
84	37.7	38.0	37.7	38.9	38.1	38.8	-
85	39.0	38.9	39.1	39.7	39.6	39.9	-
86	38.2	38.7	37.2	38.4	39.3	39.5	-
87	37.6	37.8	37.3	38.1	37.8	38.3	-
88	37.4	38.5	37.9	38.6	39.4	39.6	-
89	38.0	38.7	39.0	39.6	39.1	39.4	-
90	38.4	38.7	37.9	39.2	39.6	39.5	-
Mean	38.19	38.38	37.95	38.79	38.91	39.13	-
SD	0.52	0.42	0.57	0.47	0.63	0.48	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date		
	22	29	36
76	-	-	-
77	-	-	-
78	-	-	-
79	-	-	-
80	-	-	-
81	-	-	-
82	-	-	-
83	-	-	-
84	-	-	-
85	-	-	-
86	39.1	39.2	38.8
87	38.4	38.2	37.4
88	39.1	39.2	39.3
89	39.3	39.4	39.6
90	39.3	39.3	38.7
Mean	39.04	39.06	38.76
SD	0.37	0.49	0.84
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
106	37.1	38.1	39.0	39.1	37.2	38.8	-
107	37.5	39.0	39.2	39.2	37.7	39.3	-
108	38.2	37.2	37.5	37.9	37.2	38.7	-
109	37.7	38.5	39.0	39.1	37.6	38.4	-
110	37.9	38.5	38.7	39.3	37.9	39.1	-
111	38.0	38.8	37.2	38.3	37.8	38.3	-
112	39.1	39.9	39.5	39.6	39.0	40.0	-
113	37.7	38.5	37.7	38.6	37.7	39.3	-
114	37.2	38.0	38.8	38.6	38.6	39.8	-
115	38.1	38.0	37.0	39.2	36.9	38.2	-
116	37.4	38.9	38.0	38.4	37.2	39.4	-
117	37.2	37.8	37.2	37.6	37.4	38.6	-
118	37.4	38.6	37.7	38.2	37.6	38.7	-
119	38.2	39.0	37.7	38.7	37.4	39.7	-
120	37.3	38.2	38.0	38.1	37.2	39.3	-
Mean	37.73	38.47	38.15	38.66	37.63	39.04	-
SD	0.53	0.63	0.81	0.58	0.55	0.56	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date		
	22	29	36
106	-	-	-
107	-	-	-
108	-	-	-
109	-	-	-
110	-	-	-
111	-	-	-
112	-	-	-
113	-	-	-
114	-	-	-
115	-	-	-
116	39.0	39.5	38.8
117	38.6	39.0	38.6
118	38.8	38.4	38.3
119	38.7	38.7	39.0
120	39.5	38.6	39.0
Mean	38.92	38.84	38.74
SD	0.36	0.43	0.30
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
136	39.3	37.1	38.0	38.9	39.2	39.1	-
137	38.4	37.7	38.2	39.2	39.0	39.7	-
138	39.2	39.0	39.5	39.5	39.8	39.9	-
139	38.3	38.5	38.0	38.6	39.4	38.6	-
140	37.9	38.4	37.4	39.0	39.7	39.6	-
141	37.7	37.8	37.5	39.0	39.3	38.8	-
142	38.1	38.7	38.0	38.9	39.5	39.2	-
143	38.3	37.8	38.2	38.9	38.5	39.4	-
144	38.7	39.1	38.4	38.8	38.5	39.9	-
145	38.4	38.9	38.2	39.2	38.2	39.0	-
146	38.3	39.3	38.5	39.1	39.2	39.3	-
147	38.1	37.2	37.8	39.1	39.6	39.8	-
148	38.3	37.7	38.2	38.6	39.0	39.0	-
149	38.4	38.9	39.0	38.5	39.5	40.2	38.5
150	38.7	39.1	38.4	39.5	39.1	39.9	-
Mean	38.41	38.35	38.22	38.99	39.17	39.43	38.50
SD	0.43	0.73	0.53	0.30	0.47	0.47	-
N	15	15	15	15	15	15	1

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date		
	22	29	36
136	-	-	-
137	-	-	-
138	-	-	-
139	-	-	-
140	-	-	-
141	-	-	-
142	-	-	-
143	-	-	-
144	-	-	-
145	-	-	-
146	38.5	38.9	38.6
147	39.4	39.4	39.2
148	38.9	39.4	39.5
149	39.2	39.5	39.1
150	39.2	39.2	38.9
Mean	39.04	39.28	39.06
SD	0.35	0.24	0.34
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	3 (48h pa)	8 (4 h pa)	9 (24h pa)	15	22
166	39.5	39.1	-	39.0	39.2	-	-
167	38.1	35.7	-	37.7	38.9	-	-
168	38.0	38.8	-	38.2	38.7	-	-
169	39.6	38.5	-	38.0	38.9	-	-
170	38.6	37.1	-	37.7	38.7	-	-
171	39.6	40.0	39.2	39.6	39.4	-	-
172	38.0	38.0	-	39.6	39.8	-	-
173	38.8	38.7	-	39.2	39.4	-	-
174	38.7	38.5	-	38.6	38.7	-	-
175	38.2	36.7	-	38.0	38.5	-	-
176	38.7	38.7	-	38.3	39.2	38.8	38.8
177	39.1	39.1	-	37.8	39.5	38.7	39.0
178	39.0	37.1	-	38.3	38.1	39.1	38.8
179	38.1	36.9	-	38.0	39.1	38.8	39.2
180	38.4	38.9	-	38.6	39.4	38.1	38.7
Mean	38.69	38.12	39.20	38.44	39.03	38.70	38.90
SD	0.57	1.16	-	0.64	0.45	0.37	0.20
N	15	15	1	15	15	5	5

TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date
	29
166	-
167	-
168	-
169	-
170	-
171	-
172	-
173	-
174	-
175	-
176	39.2
177	39.1
178	39.4
179	39.2
180	38.5
Mean	39.08
SD	0.34
N	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
196	39.0	39.3	38.2	39.4	39.0	39.5	-
197	37.7	39.0	38.2	39.1	39.2	38.9	-
198	38.3	38.6	38.7	39.2	38.3	39.4	-
199	38.8	38.8	38.0	39.2	39.5	39.5	-
200	39.0	39.5	38.8	39.6	39.6	39.9	-
201	38.2	39.1	38.1	39.7	38.3	39.6	-
202	38.0	39.3	38.5	39.6	39.2	39.9	-
203	38.5	39.4	38.2	39.0	38.8	39.0	-
204	38.6	39.0	38.5	39.1	39.7	38.9	-
205	38.9	39.1	38.8	39.6	39.5	39.9	-
206	38.5	39.2	38.1	39.6	39.1	39.9	-
207	38.5	38.8	38.6	39.1	39.0	39.9	-
208	37.8	38.7	38.0	38.2	39.2	39.1	-
209	39.0	39.1	38.4	39.4	39.6	39.7	-
210	38.9	39.4	38.2	39.6	39.0	39.6	-
Mean	38.51	39.09	38.35	39.29	39.13	39.51	-
SD	0.44	0.27	0.28	0.38	0.43	0.38	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date		
	22	29	36
196	-	-	-
197	-	-	-
198	-	-	-
199	-	-	-
200	-	-	-
201	-	-	-
202	-	-	-
203	-	-	-
204	-	-	-
205	-	-	-
206	38.8	39.3	39.2
207	39.4	39.2	39.2
208	39.1	38.7	39.0
209	39.1	38.8	39.4
210	38.6	39.0	39.1
Mean	39.00	39.00	39.18
SD	0.31	0.25	0.15
N	5	5	5

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a1]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a2]
Group 1: Control	Mean	8.60	7.270	9.367	4.21	306.96	998.5	41.92
	SD	0.24	0.365	2.087	0.58	36.75	129.0	1.21
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.43	7.218	11.746	1.04**	74.85**	1021.7	40.58
	SD	0.25	0.260	2.519	0.22	14.71	131.1	1.44
	N	10	10	10	10	10	10	10
	%Diff	-2.0	-0.7	25.4	-75.3	-75.6	2.3	-3.2
Group 3: 10 µg/ animal BNT162a1	Mean	8.99*	7.754**	10.574	1.51**	116.28**	1118.6	42.77
	SD	0.42	0.371	1.841	0.34	23.50	154.1	2.03
	N	10	10	10	10	10	10	10
	%Diff	4.5	6.7	12.9	-64.1	-62.1	12.0	2.0
Group 4: 30 µg/ animal BNT162b1	Mean	8.21*	7.126	10.001	2.40	171.12**	1001.6	40.39*
	SD	0.17	0.198	2.166	0.41	28.57	126.9	0.69
	N	10	10	10	10	10	10	10
	%Diff	-4.5	-2.0	6.8	-43.0	-44.3	0.3	-3.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): * = $p \leq 0.05$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.93*	7.784**	10.911	1.45**	112.54**	1051.6	42.53
100 µg/	SD	0.23	0.249	2.388	0.35	26.19	148.2	1.17
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	3.8	7.1	16.5	-65.6	-63.3	5.3	1.5
Group 6:	Mean	8.95*	7.796**	12.886**	0.99**	77.06**	1099.3	42.66
30 µg/	SD	0.34	0.323	2.098	0.28	20.59	147.4	1.31
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	4.1	7.2	37.6	-76.5	-74.9	10.1	1.8
Group 7:	Mean	9.11**	7.848**	12.834**	1.08**	85.52**	948.9	42.88
100 µg/	SD	0.21	0.182	1.431	0.23	16.53	164.8	0.87
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	5.9	8.0	37.0	-74.3	-72.1	-5.0	2.3

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.75 n	7.708 n	20.115 n	2.49 n	192.67 n	708.8 n	41.46 n
	SD	0.37	0.319	4.492	0.50	36.61	100.9	1.90
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a1]	Reti (x10E3/µL) [a1]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	9.14	7.956	9.090	2.96	234.60	1089.2	45.03
	SD	0.25	0.232	2.418	0.37	25.66	199.5	1.21
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.67**	7.723	16.280**	2.26**	174.83**	804.7**	42.43**
	SD	0.31	0.229	3.632	0.46	33.86	148.6	1.50
	N	10	10	10	10	10	10	10
	%Diff	-5.1	-2.9	79.1	-23.6	-25.5	-26.1	-5.8
Group 3: 10 µg/ animal BNT162a1	Mean	8.69**	7.844	14.759**	2.43	190.39*	805.1**	41.10**
	SD	0.31	0.403	2.207	0.39	29.73	169.4	1.40
	N	10	10	10	10	10	10	10
	%Diff	-4.9	-1.4	62.4	-17.9	-18.8	-26.1	-8.7
Group 4: 30 µg/ animal BNT162b1	Mean	8.62**	7.751	14.612**	2.46	188.61*	930.6	42.66**
	SD	0.23	0.285	3.826	0.30	20.68	167.8	1.27
	N	10	10	10	10	10	10	10
	%Diff	-5.7	-2.6	60.7	-16.9	-19.6	-14.6	-5.3

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.14**	7.511	16.564**	3.00	223.29	817.2**	38.79**
100 µg/	SD	0.34	0.430	4.442	0.85	59.50	145.9	1.80
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-10.9	-5.6	82.2	1.4	-4.8	-25.0	-13.9
Group 7:	Mean	8.31**	7.670	19.876**	2.27**	172.94**	771.4**	39.65**
100 µg/	SD	0.33	0.307	5.114	0.41	28.95	121.1	1.55
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-9.1	-3.6	118.7	-23.3	-26.3	-29.2	-11.9

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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Three LNP-Formulated
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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.80 n	8.456 n	6.900 n	2.40 n	202.06 n	977.4 n	42.62 n
	SD	0.16	0.201	1.457	0.29	27.22	117.6	0.99
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	8.96	8.524	10.126	2.80	236.12	988.4	44.22
	SD	0.46	0.626	2.715	0.62	42.05	160.5	1.79
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	9.00	8.582	9.254	3.04	261.06	1106.4	44.34
	SD	0.20	0.134	1.545	0.34	28.05	64.9	0.67
	N	5	5	5	5	5	5	5
	%Diff	0.4	0.7	-8.6	8.6	10.6	11.9	0.3
Group 3: 10 µg/ animal BNT162a1	Mean	9.04	8.680	9.280	2.56	222.06	1040.0	44.26
	SD	0.45	0.487	2.388	0.40	26.58	185.1	1.97
	N	5	5	5	5	5	5	5
	%Diff	0.9	1.8	-8.4	-8.6	-6.0	5.2	0.1
Group 4: 30 µg/ animal BNT162b1	Mean	8.56	8.338	8.066	2.66	222.08	942.0	42.52
	SD	0.28	0.463	2.376	0.56	39.64	126.0	1.73
	N	5	5	5	5	5	5	5
	%Diff	-4.5	-2.2	-20.3	-5.0	-5.9	-4.7	-3.8

[a] - Anova & Dunnett

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.86	8.668	9.048	2.32	201.20	921.4	43.56
100 µg/	SD	0.26	0.237	1.157	0.40	40.75	76.2	1.71
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.1	1.7	-10.6	-17.1	-14.8	-6.8	-1.5
Group 7:	Mean	9.08	8.884	10.370	2.40	211.78	1027.0	44.56
100 µg/	SD	0.28	0.351	2.679	0.45	38.99	159.6	1.66
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	1.3	4.2	2.4	-14.3	-10.3	3.9	0.8

[a] - Anova & Dunnett

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	15.93	78.39	3.10	1.31	0.98	0.28
	SD	2.78	3.54	0.58	0.39	0.39	0.08
	N	10	10	10	10	10	10
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	29.05	60.74	3.42	1.04	5.46	0.33
	SD	3.79	5.51	0.82	0.34	2.17	0.08
	N	10	10	10	10	10	10
	%Diff	82.4	-22.5	10.3	-20.6	457.1	17.9
Group 3: 10 µg/ animal BNT162a1	Mean	13.58	79.92	2.80	1.14	2.11	0.44
	SD	3.45	4.56	0.62	0.41	0.69	0.10
	N	10	10	10	10	10	10
	%Diff	-14.8	2.0	-9.7	-13.0	115.3	57.1
Group 4: 30 µg/ animal BNT162b1	Mean	14.78	79.57	2.57	1.32	1.43	0.33
	SD	3.37	3.61	0.48	0.60	0.52	0.07
	N	10	10	10	10	10	10
	%Diff	-7.2	1.5	-17.1	0.8	45.9	17.9

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	12.08	82.40	1.93	1.10	2.11	0.39
100 µg/	SD	1.79	2.95	0.53	0.37	1.03	0.12
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	-24.2	5.1	-37.7	-16.0	115.3	39.3
Group 6:	Mean	19.64	72.80	3.18	0.75	3.17	0.45
30 µg/	SD	2.52	3.68	1.07	0.24	1.76	0.10
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	23.3	-7.1	2.6	-42.7	223.5	60.7
Group 7:	Mean	15.79	77.95	2.15	0.86	2.76	0.49
100 µg/	SD	6.43	7.77	0.61	0.46	0.75	0.07
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	-0.9	-0.6	-30.6	-34.4	181.6	75.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	44.37	44.33	3.18	0.48	7.18	0.47
	SD	7.23	8.32	1.06	0.18	2.61	0.22
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	16.11	77.96	3.38	1.27	0.95	0.32
	SD	6.39	6.57	0.63	0.34	0.28	0.09
	N	10	10	10	10	10	10
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	47.63	41.20	3.47	0.61	6.73	0.37
	SD	4.39	4.79	0.60	0.17	3.16	0.13
	N	10	10	10	10	10	10
	%Diff	195.7	-47.2	2.7	-52.0	608.4	15.6
Group 3: 10 µg/ animal BNT162a1	Mean	36.56	54.82	4.18	0.75	3.25	0.46
	SD	5.18	4.57	1.32	0.31	1.06	0.08
	N	10	10	10	10	10	10
	%Diff	126.9	-29.7	23.7	-40.9	242.1	43.8
Group 4: 30 µg/ animal BNT162b1	Mean	40.64	51.38	4.35	1.64	1.61	0.41
	SD	6.72	6.71	1.39	0.36	0.32	0.12
	N	10	10	10	10	10	10
	%Diff	152.3	-34.1	28.7	29.1	69.5	28.1

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	46.94	43.82	3.34	2.21	3.32	0.37
100 µg/	SD	6.74	7.90	0.94	0.64	1.32	0.07
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	191.4	-43.8	-1.2	74.0	249.5	15.6
Group 7:	Mean	51.91	39.18	2.53	2.83	3.21	0.34
100 µg/	SD	3.40	4.27	0.98	0.71	1.46	0.13
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	222.2	-49.7	-25.1	122.8	237.9	6.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	21.10	73.18	3.14	1.54	0.82	0.22
	SD	2.21	2.59	0.56	0.17	0.19	0.08
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	17.54	76.02	3.32	1.78	1.08	0.28
	SD	2.88	3.69	0.80	0.63	0.25	0.04
	N	5	5	5	5	5	5
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	15.26	77.78	3.74	1.48	1.46	0.30
	SD	2.29	1.62	0.77	0.48	0.44	0.10
	N	5	5	5	5	5	5
	%Diff	-13.0	2.3	12.7	-16.9	35.2	7.1
Group 3: 10 µg/ animal BNT162a1	Mean	15.74	78.58	2.98	1.54	0.92	0.20
	SD	3.35	4.11	0.89	0.54	0.19	0.07
	N	5	5	5	5	5	5
	%Diff	-10.3	3.4	-10.2	-13.5	-14.8	-28.6
Group 4: 30 µg/ animal BNT162b1	Mean	19.94	73.28	3.54	2.02	1.00	0.26
	SD	5.77	5.50	0.86	0.34	0.29	0.05
	N	5	5	5	5	5	5
	%Diff	13.7	-3.6	6.6	13.5	-7.4	-7.1

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	19.86	74.82	2.52	1.68	0.86	0.24
100 µg/	SD	3.93	4.17	0.39	0.70	0.21	0.11
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	13.2	-1.6	-24.1	-5.6	-20.4	-14.3
Group 7:	Mean	17.94	75.84	3.10	1.76	1.10	0.28
100 µg/	SD	6.72	7.21	0.84	0.57	0.44	0.04
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	2.3	-0.2	-6.6	-1.1	1.9	0.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a1]
Group 1: Control	Mean	1.499	7.338	0.292	0.121	0.089	0.026
	SD	0.458	1.608	0.097	0.037	0.026	0.012
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	3.430**	7.087	0.406	0.121	0.663**	0.038
	SD	0.888	1.507	0.144	0.051	0.305	0.018
	N	10	10	10	10	10	10
	%Diff	128.8	-3.4	39.0	0.0	644.9	46.2
Group 3: 10 µg/ animal BNT162a1	Mean	1.414	8.479	0.296	0.119	0.219**	0.047*
	SD	0.355	1.682	0.080	0.041	0.073	0.018
	N	10	10	10	10	10	10
	%Diff	-5.7	15.5	1.4	-1.7	146.1	80.8
Group 4: 30 µg/ animal BNT162b1	Mean	1.464	7.976	0.255	0.124	0.146	0.035
	SD	0.407	1.830	0.067	0.042	0.079	0.014
	N	10	10	10	10	10	10
	%Diff	-2.3	8.7	-12.7	2.5	64.0	34.6

[a] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.317	8.996	0.209	0.119	0.224**	0.042
100 µg/	SD	0.340	2.006	0.076	0.055	0.097	0.019
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	-12.1	22.6	-28.4	-1.7	151.7	61.5
Group 6:	Mean	2.524**	9.393*	0.405	0.097	0.410**	0.060**
30 µg/	SD	0.478	1.671	0.152	0.029	0.210	0.020
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	68.4	28.0	38.7	-19.8	360.7	130.8
Group 7:	Mean	1.998	10.039**	0.273	0.110	0.352**	0.065**
100 µg/	SD	0.755	1.733	0.082	0.059	0.092	0.014
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	33.3	36.8	-6.5	-9.1	295.5	150.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.793 n	9.110 n	0.632 n	0.094 n	1.384 n	0.102 n
	SD	1.767	3.446	0.232	0.037	0.455	0.078
	N	10	10	10	10	10	10
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a1]	Eos (x10E3/µL) [a2]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	1.458	7.094	0.308	0.109	0.088	0.030
	SD	0.707	2.057	0.102	0.014	0.051	0.014
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	7.736**	6.645	0.569*	0.101	1.167**	0.063**
	SD	1.803	1.466	0.184	0.036	0.672	0.029
	N	10	10	10	10	10	10
	%Diff	430.6	-6.3	84.7	-7.3	1226.1	110.0
Group 3: 10 µg/ animal BNT162a1	Mean	5.353**	8.116	0.627**	0.106	0.489**	0.069**
	SD	0.805	1.525	0.241	0.030	0.197	0.017
	N	10	10	10	10	10	10
	%Diff	267.1	14.4	103.6	-2.8	455.7	130.0
Group 4: 30 µg/ animal BNT162b1	Mean	5.893**	7.564	0.623**	0.231**	0.237**	0.060**
	SD	1.610	2.424	0.227	0.049	0.088	0.034
	N	10	10	10	10	10	10
	%Diff	304.2	6.6	102.3	111.9	169.3	100.0

[a] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	7.980**	7.021	0.548*	0.360**	0.594**	0.063**
100 µg/	SD	3.197	1.113	0.184	0.119	0.453	0.025
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	447.3	-1.0	77.9	230.3	575.0	110.0
Group 7:	Mean	10.291**	7.752	0.502	0.566**	0.691**	0.074**
100 µg/	SD	2.545	2.029	0.230	0.199	0.468	0.040
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	605.8	9.3	63.0	419.3	685.2	146.7

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.470 n	5.034 n	0.216 n	0.106 n	0.060 n	0.016 n
	SD	0.420	0.984	0.062	0.023	0.016	0.009
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a1]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	1.806	7.638	0.352	0.194	0.106	0.028
	SD	0.724	1.735	0.185	0.116	0.027	0.015
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.404	7.194	0.350	0.138	0.138	0.028
	SD	0.268	1.173	0.119	0.055	0.056	0.008
	N	5	5	5	5	5	5
	%Diff	-22.3	-5.8	-0.6	-28.9	30.2	0.0
Group 3: 10 µg/ animal BNT162a1	Mean	1.410	7.358	0.268	0.134	0.090	0.018
	SD	0.196	2.272	0.057	0.030	0.041	0.013
	N	5	5	5	5	5	5
	%Diff	-21.9	-3.7	-23.9	-30.9	-15.1	-35.7
Group 4: 30 µg/ animal BNT162b1	Mean	1.530	5.984	0.286	0.160	0.082	0.020
	SD	0.362	2.049	0.113	0.056	0.033	0.010
	N	5	5	5	5	5	5
	%Diff	-15.3	-21.7	-18.8	-17.5	-22.6	-28.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.798	6.768	0.224	0.158	0.076	0.022
100 µg/	SD	0.458	0.935	0.013	0.077	0.025	0.013
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-0.4	-11.4	-36.4	-18.6	-28.3	-21.4
Group 7:	Mean	1.830	7.906	0.310	0.180	0.114	0.030
100 µg/	SD	0.623	2.412	0.069	0.080	0.053	0.016
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	1.3	3.5	-11.9	-7.2	7.5	7.1

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 1: Control	Mean	57.74	1.184	20.490
	SD	2.12	0.042	0.150
	N	10	10	10
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	56.24	1.167	20.782*
	SD	1.48	0.028	0.244
	N	10	10	10
	%Diff	-2.6	-1.4	1.4
Group 3: 10 µg/ animal BNT162a1	Mean	55.19**	1.161	21.034**
	SD	1.16	0.028	0.286
	N	10	10	10
	%Diff	-4.4	-1.9	2.7
Group 4: 30 µg/ animal BNT162b1	Mean	56.73	1.154	20.362
	SD	1.55	0.025	0.229
	N	10	10	10
	%Diff	-1.7	-2.5	-0.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	54.63**	1.149	21.039**
	SD	0.93	0.025	0.261
	N	10	10	10
	%Diff	-5.4	-3.0	2.7
Group 6: 30 µg/ animal BNT162c1	Mean	54.75**	1.150	20.990**
	SD	1.44	0.026	0.256
	N	10	10	10
	%Diff	-5.2	-2.9	2.4
Group 7: 100 µg/ animal BNT162b2	Mean	54.68**	1.162	21.252**
	SD	1.38	0.023	0.266
	N	10	10	10
	%Diff	-5.3	-1.9	3.7

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.91 n	18.25 n	298.20 n	53.80 n	1.133 n	21.070 n
	SD	0.39	0.78	18.63	1.59	0.021	0.364
	N	10	10	10	10	10	10
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a2]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 1: Control	Mean	9.57	15.32	106.12	56.61	1.151	20.319
	SD	0.22	1.79	9.55	1.67	0.029	0.270
	N	9	9	9	10	10	10
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	9.49	17.70**	309.10**	54.96*	1.122	20.403
	SD	0.60	1.40	23.06	1.03	0.017	0.253
	N	10	10	10	10	10	10
	%Diff	-0.8	15.5	191.3	-2.9	-2.5	0.4
Group 3: 10 µg/ animal BNT162a1	Mean	9.70	18.11**	271.00**	52.48**	1.110**	21.153**
	SD	0.37	1.31	22.32	1.47	0.028	0.239
	N	9	9	9	10	10	10
	%Diff	1.4	18.2	155.4	-7.3	-3.6	4.1
Group 4: 30 µg/ animal BNT162b1	Mean	9.56	14.59	271.40**	55.07*	1.113**	20.217
	SD	0.33	0.54	22.57	0.97	0.025	0.305
	N	10	10	10	10	10	10
	%Diff	-0.1	-4.8	155.7	-2.7	-3.3	-0.5

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	9.33	16.82	310.00**	51.69**	1.085**	20.998**
100 µg/	SD	0.51	1.17	11.81	1.20	0.022	0.336
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	-2.5	9.8	192.1	-8.7	-5.7	3.3
Group 7:	Mean	9.38	17.49*	323.90**	51.72**	1.082**	20.963**
100 µg/	SD	0.45	1.22	27.56	1.43	0.029	0.209
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	-2.0	14.1	205.2	-8.6	-6.0	3.2

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.76 n	14.58 n	140.80 n	50.42 n	1.038 n	20.628 n
	SD	0.47	1.03	55.98	0.61	0.025	0.297
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a1]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 1: Control	Mean	9.42	15.74	164.34	52.00	1.054	20.280
	SD	0.32	0.90	75.46	1.82	0.034	0.184
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.94	15.78	95.52	51.68	1.052	20.318
	SD	0.38	0.70	7.40	1.08	0.029	0.201
	N	5	5	5	5	5	5
	%Diff	5.5	0.3	-41.9	-0.6	-0.2	0.2
Group 3: 10 µg/ animal BNT162a1	Mean	9.70	15.64	127.80	51.00	1.040	20.378
	SD	0.20	1.23	71.17	1.04	0.020	0.275
	N	5	5	5	5	5	5
	%Diff	3.0	-0.6	-22.2	-1.9	-1.3	0.5
Group 4: 30 µg/ animal BNT162b1	Mean	9.88	15.22	102.90	51.04	1.028	20.106
	SD	0.18	0.24	10.75	1.65	0.029	0.322
	N	5	5	5	5	5	5
	%Diff	4.9	-3.3	-37.4	-1.8	-2.5	-0.9

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	9.60	16.46	132.82	50.22	1.020	20.332
100 µg/	SD	0.37	2.24	72.39	0.80	0.007	0.170
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	1.9	4.6	-19.2	-3.4	-3.2	0.3
Group 7:	Mean	9.60	15.90	103.76	50.16	1.024	20.408
100 µg/	SD	0.50	1.55	15.93	0.74	0.023	0.294
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	1.9	1.0	-36.9	-3.5	-2.8	0.6

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a1]
Group 1: Control	Mean	7.91	0.790	71.43	12.48	20.69
	SD	0.79	0.108	10.12	0.51	1.31
	N	10	10	10	10	10
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	8.25	0.840	89.37**	13.25**	22.78**
	SD	0.63	0.092	4.39	0.32	1.18
	N	10	10	10	10	10
	%Diff	4.3	6.3	25.1	6.2	10.1
Group 3: 10 µg/ animal BNT162a1	Mean	7.43	0.824	83.89**	12.06	23.49**
	SD	0.76	0.089	6.30	0.48	0.91
	N	10	10	10	10	10
	%Diff	-6.1	4.3	17.4	-3.4	13.5
Group 4: 30 µg/ animal BNT162b1	Mean	8.15	0.814	75.39	12.88	21.21
	SD	0.61	0.099	7.01	0.49	1.15
	N	10	10	10	10	10
	%Diff	3.0	3.0	5.5	3.2	2.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	7.78	0.818	81.43*	12.14	23.38**
100 µg/	SD	0.53	0.115	8.09	0.36	1.41
animal	N	10	10	10	10	10
BNT162b1	%Diff	-1.6	3.5	14.0	-2.7	13.0
Group 6:	Mean	7.98	0.876	88.08**	12.21	23.58**
30 µg/	SD	0.71	0.126	8.19	0.33	0.39
animal	N	10	10	10	10	10
BNT162c1	%Diff	0.9	10.9	23.3	-2.2	14.0
Group 7:	Mean	8.48	0.803	89.07**	12.03	23.96**
100 µg/	SD	0.47	0.119	8.48	0.32	1.49
animal	N	10	10	10	10	10
BNT162b2	%Diff	7.2	1.6	24.7	-3.6	15.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.55n	0.673n	94.97n	13.32n	22.61n
	SD	1.01	0.110	6.21	0.42	1.39
	N	10	10	10	10	10
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a1]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	10.91	1.180	56.59	15.17	18.09
	SD	0.88	0.190	2.67	0.74	0.99
	N	10	10	10	10	10
	-					
Group 2: 30 µg/ animal BNT162a1	Mean	11.79	0.941**	70.88**	16.27**	19.73**
	SD	0.90	0.157	6.33	0.54	0.85
	N	10	10	10	10	10
	%Diff	8.1	-20.3	25.3	7.3	9.1
Group 3: 10 µg/ animal BNT162a1	Mean	8.68**	0.690**	84.87**	13.32**	21.21**
	SD	0.81	0.096	6.09	0.62	1.16
	N	10	10	10	10	10
	%Diff	-20.4	-41.5	50.0	-12.2	17.2
Group 4: 30 µg/ animal BNT162b1	Mean	11.55	1.072	61.40*	16.52**	18.64
	SD	0.83	0.188	2.91	0.76	0.82
	N	10	10	10	10	10
	%Diff	5.9	-9.2	8.5	8.9	3.0

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	9.04**	0.733**	83.22**	13.32**	21.61**
100 µg/	SD	0.69	0.094	5.76	0.66	0.90
animal	N	10	10	10	10	10
BNT162b1	%Diff	-17.1	-37.9	47.1	-12.2	19.5
Group 7:	Mean	9.36**	0.723**	82.52**	13.35**	21.48**
100 µg/	SD	0.66	0.125	3.31	0.59	0.99
animal	N	10	10	10	10	10
BNT162b2	%Diff	-14.2	-38.7	45.8	-12.0	18.7

[a] - Anova & Dunnett: ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	7.94 n	0.778 n	70.16 n	13.04 n	20.22 n
	SD	0.48	0.131	6.56	0.44	1.10
	N	5	5	5	5	5
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	8.86	0.866	68.38	11.50	18.90
	SD	0.86	0.106	2.85	0.69	0.85
	N	5	5	5	5	5
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	8.14	0.902	67.70	13.54**	19.56
	SD	0.43	0.072	4.18	0.36	1.14
	N	5	5	5	5	5
	%Diff	-8.1	4.2	-1.0	17.7	3.5
Group 3: 10 µg/ animal BNT162a1	Mean	8.00	0.830	70.42	13.66**	20.34
	SD	0.51	0.112	9.60	0.34	1.02
	N	5	5	5	5	5
	%Diff	-9.7	-4.2	3.0	18.8	7.6
Group 4: 30 µg/ animal BNT162b1	Mean	8.44	0.786	69.08	13.44**	19.62
	SD	0.89	0.083	7.39	0.57	1.09
	N	5	5	5	5	5
	%Diff	-4.7	-9.2	1.0	16.9	3.8

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	8.46	0.774	73.32	13.34**	19.50
100 µg/	SD	1.00	0.054	8.40	0.42	1.54
animal	N	5	5	5	5	5
BNT162b1	%Diff	-4.5	-10.6	7.2	16.0	3.2
Group 7:	Mean	8.16	0.842	69.26	13.26**	19.80
100 µg/	SD	0.25	0.143	7.23	0.53	1.15
animal	N	5	5	5	5	5
BNT162b2	%Diff	-7.9	-2.8	1.3	15.3	4.8

[a] - Anova & Dunnett: ** = p ≤ 0.01

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a1]	Reti (%) [a]	Reti (x10E3/µL) [a1]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	8.87	7.654	8.417	2.56	195.69	975.1	41.87
	SD	0.46	0.344	3.256	0.47	33.93	150.4	2.45
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.57	7.295	12.893**	0.97**	69.75**	753.6*	40.41
	SD	0.36	0.334	1.660	0.36	23.24	133.3	1.69
	N	10	10	10	10	10	10	10
	%Diff	-3.4	-4.7	53.2	-62.1	-64.4	-22.7	-3.5
Group 3: 10 µg/ animal BNT162a1	Mean	9.12	7.807	8.719	1.23**	94.88**	1068.3	42.23
	SD	0.36	0.409	2.464	0.35	23.30	242.8	1.90
	N	10	10	10	10	10	10	10
	%Diff	2.8	2.0	3.6	-52.0	-51.5	9.6	0.9
Group 4: 30 µg/ animal BNT162b1	Mean	8.70	7.506	8.311	1.92**	143.85*	985.7	41.39
	SD	0.33	0.474	1.844	0.57	44.93	128.7	1.79
	N	10	10	10	10	10	10	10
	%Diff	-1.9	-1.9	-1.3	-25.0	-26.5	1.1	-1.1

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): * = p ≤ 0.05; ** = p ≤ 0.01

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.62	7.589	9.049	1.47**	112.33**	1048.6	40.49
100 µg/	SD	0.32	0.262	1.822	0.28	20.92	125.9	1.54
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-2.8	-0.8	7.5	-42.6	-42.6	7.5	-3.3
Group 6:	Mean	8.78	7.576	10.029	1.05**	79.63**	1000.2	40.31
30 µg/	SD	0.36	0.339	2.855	0.18	12.83	145.2	1.49
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-1.0	-1.0	19.2	-59.0	-59.3	2.6	-3.7
Group 7:	Mean	8.74	7.578	10.395	1.34**	101.31**	1016.5	40.15
100 µg/	SD	0.35	0.440	2.908	0.33	28.82	116.2	1.80
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-1.5	-1.0	23.5	-47.7	-48.2	4.2	-4.1

[a] - Anova & Dunnett: ** = p ≤ 0.01

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.43 n	7.419 n	15.267 n	2.53 n	184.44 n	570.4 n	38.86 n
	SD	0.33	0.508	2.493	0.73	44.08	145.4	1.55
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	9.08	7.892	7.106	2.56	200.95	1068.1	43.45
	SD	0.36	0.213	2.414	0.53	38.85	140.4	1.83
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.66	7.546	14.500**	2.64	199.77	622.9**	41.74
	SD	0.34	0.340	4.114	0.69	50.73	155.2	1.92
	N	10	10	10	10	10	10	10
	%Diff	-4.6	-4.4	104.1	3.1	-0.6	-41.7	-3.9
Group 3: 10 µg/ animal BNT162a1	Mean	8.38**	7.465*	11.016*	3.04	225.54	698.1**	39.24**
	SD	0.32	0.298	2.490	0.92	66.10	166.4	1.56
	N	10	10	10	10	10	10	10
	%Diff	-7.7	-5.4	55.0	18.8	12.2	-34.6	-9.7
Group 4: 30 µg/ animal BNT162b1	Mean	8.13**	7.248**	12.744**	2.89	209.89	876.8*	39.50**
	SD	0.34	0.296	3.637	0.60	38.31	117.1	1.44
	N	10	10	10	10	10	10	10
	%Diff	-10.5	-8.2	79.3	12.9	4.4	-17.9	-9.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	7.85**	7.145**	14.405**	3.18	226.66	702.2**	37.06**
100 µg/	SD	0.50	0.355	2.642	0.70	43.09	116.6	2.38
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-13.5	-9.5	102.7	24.2	12.8	-34.3	-14.7
Group 7:	Mean	7.93**	7.115**	14.997**	2.78	197.95	704.4**	37.59**
100 µg/	SD	0.35	0.288	3.215	0.58	36.41	148.3	1.81
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-12.7	-9.8	111.0	8.6	-1.5	-34.1	-13.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.84 n	8.142 n	5.514 n	3.06 n	248.30 n	1025.8 n	42.12 n
	SD	0.18	0.352	1.521	0.60	42.44	137.3	1.12
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	8.80	8.176	6.084	3.20	259.88	949.8	42.50
	SD	0.31	0.238	1.403	0.76	55.32	265.6	1.58
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.66	7.910	7.622	3.00	236.40	940.4	42.34
	SD	0.40	0.407	2.997	1.10	74.87	136.3	1.89
	N	5	5	5	5	5	5	5
	%Diff	-1.6	-3.3	25.3	-6.3	-9.0	-1.0	-0.4
Group 3: 10 µg/ animal BNT162a1	Mean	9.04	8.312	7.012	2.28	189.54	992.8	43.64
	SD	0.24	0.312	2.164	0.43	40.57	194.6	0.94
	N	5	5	5	5	5	5	5
	%Diff	2.7	1.7	15.3	-28.8	-27.1	4.5	2.7
Group 4: 30 µg/ animal BNT162b1	Mean	9.00	8.558	7.282	2.58	219.42	825.0	43.70
	SD	0.38	0.595	2.998	0.35	18.25	70.3	2.15
	N	5	5	5	5	5	5	5
	%Diff	2.3	4.7	19.7	-19.4	-15.6	-13.1	2.8

[a] - Anova & Dunnett

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.70	8.122	6.830	2.32	187.36	891.4	42.32
100 µg/	SD	0.34	0.443	2.050	0.86	61.82	140.1	1.60
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.1	-0.7	12.3	-27.5	-27.9	-6.1	-0.4
Group 7:	Mean	8.96	8.446	7.120	2.26	190.28	998.4	43.56
100 µg/	SD	0.18	0.428	2.398	0.50	40.16	134.0	0.98
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	1.8	3.3	17.0	-29.4	-26.8	5.1	2.5

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	14.63	80.11	2.35	1.68	0.95	0.28
	SD	6.24	7.20	0.76	0.90	0.28	0.10
	N	10	10	10	10	10	10
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	29.64	60.59	3.35	1.38	4.56	0.45
	SD	3.57	3.27	0.87	0.45	1.85	0.07
	N	10	10	10	10	10	10
	%Diff	102.6	-24.4	42.6	-17.9	380.0	60.7
Group 3: 10 µg/ animal BNT162a1	Mean	12.96	80.53	2.71	1.25	2.16	0.37
	SD	3.62	4.40	0.66	0.41	0.60	0.09
	N	10	10	10	10	10	10
	%Diff	-11.4	0.5	15.3	-25.6	127.4	32.1
Group 4: 30 µg/ animal BNT162b1	Mean	13.51	80.74	2.17	1.94	1.28	0.35
	SD	3.00	2.85	0.39	0.90	0.23	0.10
	N	10	10	10	10	10	10
	%Diff	-7.7	0.8	-7.7	15.5	34.7	25.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	18.07	74.98	2.22	1.16	3.18	0.36
100 µg/	SD	7.76	9.53	0.59	0.43	2.32	0.10
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	23.5	-6.4	-5.5	-31.0	234.7	28.6
Group 6:	Mean	22.94	68.08	3.68	1.45	3.39	0.44
30 µg/	SD	3.18	3.41	0.86	0.66	1.06	0.12
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	56.8	-15.0	56.6	-13.7	256.8	57.1
Group 7:	Mean	23.67	68.70	2.20	1.58	3.47	0.39
100 µg/	SD	6.09	7.33	0.73	0.63	1.58	0.09
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	61.8	-14.2	-6.4	-6.0	265.3	39.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	43.23	47.54	2.53	0.59	5.74	0.37
	SD	6.69	6.97	0.69	0.22	1.20	0.11
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	14.55	80.19	2.71	1.28	1.00	0.23
	SD	5.97	6.30	0.59	0.40	0.35	0.08
	N	10	10	10	10	10	10
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	44.23	46.59	2.40	0.71	5.65	0.42
	SD	7.15	7.68	0.82	0.18	2.28	0.11
	N	10	10	10	10	10	10
	%Diff	204.0	-41.9	-11.4	-44.5	465.0	82.6
Group 3: 10 µg/ animal BNT162a1	Mean	38.09	51.89	4.03	1.46	4.18	0.37
	SD	5.11	5.85	0.78	1.09	2.42	0.11
	N	10	10	10	10	10	10
	%Diff	161.8	-35.3	48.7	14.1	318.0	60.9
Group 4: 30 µg/ animal BNT162b1	Mean	42.95	47.52	3.49	2.50	3.24	0.32
	SD	9.45	9.74	0.81	0.69	1.07	0.06
	N	10	10	10	10	10	10
	%Diff	195.2	-40.7	28.8	95.3	224.0	39.1

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	48.05	41.13	2.82	3.52	4.20	0.30
100 µg/	SD	6.00	6.95	0.63	0.93	1.82	0.08
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	230.2	-48.7	4.1	175.0	320.0	30.4
Group 7:	Mean	48.70	41.65	2.01	3.80	3.59	0.26
100 µg/	SD	8.05	8.29	0.59	1.03	1.17	0.05
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	234.7	-48.1	-25.8	196.9	259.0	13.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	14.32	79.76	2.78	2.00	0.94	0.24
	SD	3.47	4.06	0.72	0.78	0.29	0.09
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	15.58	77.06	3.12	3.06	0.98	0.24
	SD	5.05	6.10	0.66	2.05	0.30	0.05
	N	5	5	5	5	5	5
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	15.88	78.66	2.52	1.58	1.12	0.26
	SD	2.77	2.35	0.64	0.44	0.34	0.09
	N	5	5	5	5	5	5
	%Diff	1.9	2.1	-19.2	-48.4	14.3	8.3
Group 3: 10 µg/ animal BNT162a1	Mean	14.96	78.66	3.12	2.06	1.00	0.22
	SD	3.15	4.86	0.70	1.78	0.28	0.11
	N	5	5	5	5	5	5
	%Diff	-4.0	2.1	0.0	-32.7	2.0	-8.3
Group 4: 30 µg/ animal BNT162b1	Mean	18.62	74.60	3.04	2.42	1.10	0.22
	SD	4.94	5.81	0.55	1.53	0.37	0.08
	N	5	5	5	5	5	5
	%Diff	19.5	-3.2	-2.6	-20.9	12.2	-8.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	18.20	75.92	3.22	1.50	0.96	0.18
100 µg/	SD	5.42	5.59	0.64	0.20	0.17	0.08
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	16.8	-1.5	3.2	-51.0	-2.0	-25.0
Group 7:	Mean	17.80	76.60	2.40	2.04	0.92	0.26
100 µg/	SD	3.87	4.05	0.34	0.69	0.18	0.09
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	14.2	-0.6	-23.1	-33.3	-6.1	8.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a1]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	1.112	6.872	0.190	0.134	0.087	0.026
	SD	0.328	3.137	0.067	0.058	0.059	0.018
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	3.837**	7.798	0.436**	0.175	0.587**	0.057**
	SD	0.761	0.963	0.150	0.050	0.239	0.013
	N	10	10	10	10	10	10
	%Diff	245.1	13.5	129.5	30.6	574.7	119.2
Group 3: 10 µg/ animal BNT162a1	Mean	1.109	7.055	0.228	0.104	0.186**	0.036
	SD	0.388	2.172	0.064	0.035	0.072	0.018
	N	10	10	10	10	10	10
	%Diff	-0.3	2.7	20.0	-22.4	113.8	38.5
Group 4: 30 µg/ animal BNT162b1	Mean	1.125	6.709	0.183	0.158	0.108	0.030
	SD	0.346	1.515	0.059	0.065	0.033	0.014
	N	10	10	10	10	10	10
	%Diff	1.2	-2.4	-3.7	17.9	24.1	15.4

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank)

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.734	6.663	0.204	0.107	0.305**	0.033
100 µg/	SD	1.075	0.964	0.070	0.047	0.270	0.012
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	55.9	-3.0	7.4	-20.1	250.6	26.9
Group 6:	Mean	2.278**	6.865	0.368**	0.137	0.334**	0.047**
30 µg/	SD	0.619	2.142	0.128	0.040	0.130	0.017
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	104.9	-0.1	93.7	2.2	283.9	80.8
Group 7:	Mean	2.523**	7.082	0.223	0.162	0.365**	0.043*
100 µg/	SD	1.276	1.693	0.077	0.074	0.205	0.016
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	126.9	3.1	17.4	20.9	319.5	65.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	6.552 n	7.308 n	0.386 n	0.092 n	0.870 n	0.055 n
	SD	1.209	1.937	0.118	0.038	0.215	0.021
	N	10	10	10	10	10	10
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a1]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a2]
Group 1: Control	Mean	0.945	5.784	0.189	0.094	0.077	0.019
	SD	0.228	2.222	0.063	0.048	0.044	0.009
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	6.515**	6.586	0.373*	0.099	0.864**	0.060**
	SD	2.556	1.428	0.239	0.032	0.511	0.028
	N	10	10	10	10	10	10
	%Diff	589.4	13.9	97.4	5.3	1022.1	215.8
Group 3: 10 µg/ animal BNT162a1	Mean	4.139**	5.771	0.438**	0.152*	0.478**	0.039*
	SD	0.842	1.657	0.119	0.088	0.330	0.014
	N	10	10	10	10	10	10
	%Diff	338.0	-0.2	131.7	61.7	520.8	105.3
Group 4: 30 µg/ animal BNT162b1	Mean	5.539**	5.982	0.443**	0.308**	0.429**	0.042**
	SD	2.191	1.845	0.183	0.088	0.214	0.020
	N	10	10	10	10	10	10
	%Diff	486.1	3.4	134.4	227.7	457.1	121.1

[a] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	6.958**	5.865	0.404**	0.508**	0.627**	0.043**
100 µg/	SD	1.735	1.083	0.129	0.152	0.354	0.018
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	636.3	1.4	113.8	440.4	714.3	126.3
Group 7:	Mean	7.369**	6.174	0.305	0.573**	0.535**	0.039*
100 µg/	SD	2.215	1.707	0.135	0.182	0.200	0.014
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	679.8	6.7	61.4	509.6	594.8	105.3

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	0.802 n	4.384 n	0.160 n	0.104 n	0.050 n	0.014 n
	SD	0.344	1.134	0.090	0.035	0.016	0.005
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	0.938	4.712	0.186	0.170	0.060	0.014
	SD	0.301	1.330	0.052	0.103	0.029	0.005
	N	5	5	5	5	5	5
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	1.176	6.014	0.200	0.120	0.088	0.022
	SD	0.465	2.369	0.113	0.052	0.037	0.013
	N	5	5	5	5	5	5
	%Diff	25.4	27.6	7.5	-29.4	46.7	57.1
Group 3: 10 µg/ animal BNT162a1	Mean	1.008	5.566	0.222	0.126	0.072	0.014
	SD	0.223	1.919	0.100	0.076	0.037	0.011
	N	5	5	5	5	5	5
	%Diff	7.5	18.1	19.4	-25.9	20.0	0.0
Group 4: 30 µg/ animal BNT162b1	Mean	1.268	5.536	0.220	0.158	0.080	0.016
	SD	0.306	2.583	0.086	0.073	0.051	0.015
	N	5	5	5	5	5	5
	%Diff	35.2	17.5	18.3	-7.1	33.3	14.3

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.160	5.274	0.212	0.106	0.064	0.012
100 µg/	SD	0.115	2.004	0.047	0.039	0.023	0.008
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	23.7	11.9	14.0	-37.6	6.7	-14.3
Group 7:	Mean	1.224	5.502	0.168	0.140	0.064	0.018
100 µg/	SD	0.357	2.067	0.061	0.050	0.024	0.008
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	30.5	16.8	-9.7	-17.6	6.7	28.6

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a1]	MCHC (mmol/L) [a1]
Group 1: Control	Mean	54.73	1.159	21.189
	SD	1.93	0.035	0.234
	N	10	10	10
		-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	55.43	1.176	21.240
	SD	1.03	0.015	0.223
	N	10	10	10
	%Diff	1.3	1.5	0.2
Group 3: 10 µg/ animal BNT162a1	Mean	54.13	1.170	21.606**
	SD	1.36	0.028	0.281
	N	10	10	10
	%Diff	-1.1	0.9	2.0
Group 4: 30 µg/ animal BNT162b1	Mean	55.21	1.162	21.069
	SD	1.77	0.040	0.264
	N	10	10	10
	%Diff	0.9	0.3	-0.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	53.35	1.138	21.319
	SD	1.61	0.039	0.284
	N	10	10	10
	%Diff	-2.5	-1.8	0.6
Group 6: 30 µg/ animal BNT162c1	Mean	53.25	1.158	21.738**
	SD	1.78	0.040	0.286
	N	10	10	10
	%Diff	-2.7	-0.1	2.6
Group 7: 100 µg/ animal BNT162b2	Mean	53.02	1.157	21.833*
	SD	1.91	0.065	1.040
	N	10	10	10
	%Diff	-3.1	-0.2	3.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.44 n	18.68 n	267.30 n	52.48 n	1.140 n	21.700 n
	SD	0.36	0.72	23.49	1.91	0.039	0.193
	N	10	10	10	10	10	10
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a]	MCV (fL) [a1]	MCH (fmol) [a1]	MCHC (mmol/L) [a1]
Group 1: Control	Mean	9.03	15.08	114.44	55.04	1.149	20.880
	SD	0.40	1.24	58.30	1.43	0.025	0.237
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.13	17.59**	314.00**	55.30	1.149	20.777
	SD	0.47	1.11	24.64	0.94	0.018	0.224
	N	10	10	10	10	10	10
	%Diff	1.1	16.6	174.4	0.5	0.0	-0.5
Group 3: 10 µg/ animal BNT162a1	Mean	8.70	18.59**	279.78*	52.58**	1.121	21.328**
	SD	1.32	1.42	63.93	1.84	0.037	0.362
	N	9	9	9	10	10	10
	%Diff	-3.7	23.3	144.5	-4.5	-2.4	2.1
Group 4: 30 µg/ animal BNT162b1	Mean	9.34	14.74	281.78**	54.53	1.120	20.554*
	SD	0.39	0.70	26.36	2.02	0.043	0.230
	N	9	9	9	10	10	10
	%Diff	3.5	-2.2	146.2	-0.9	-2.5	-1.6

[a] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	9.24	17.15**	299.10**	51.86**	1.100**	21.221*
100 µg/	SD	0.53	1.38	32.24	1.49	0.029	0.273
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	2.3	13.7	161.4	-5.8	-4.3	1.6
Group 7:	Mean	9.39	17.81**	297.75**	52.84*	1.116	21.098
100 µg/	SD	0.44	1.01	15.50	1.27	0.023	0.331
animal	N	8	8	8	10	10	10
BNT162b2	%Diff	4.0	18.1	160.2	-4.0	-2.9	1.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.28 n	15.32 n	104.00 n	51.78 n	1.086 n	20.992 n
	SD	0.60	1.09	29.23	1.18	0.036	0.367
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a2]	MCV (fL) [a1]	MCH (fmol) [a1]	MCHC (mmol/L) [a2]
Group 1: Control	Mean	9.34	17.05	88.25	52.00	1.078	20.718
	SD	0.63	0.64	7.69	1.97	0.030	0.160
	N	5	4	4	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.36	15.58	86.78	53.58	1.094	20.402
	SD	0.29	0.80	4.08	1.72	0.025	0.231
	N	5	4	4	5	5	5
	%Diff	0.2	-8.7	-1.7	3.0	1.5	-1.5
Group 3: 10 µg/ animal BNT162a1	Mean	9.26	17.52	116.98	52.50	1.086	20.706
	SD	0.27	1.43	70.19	1.34	0.022	0.205
	N	5	5	4	5	5	5
	%Diff	-0.9	2.8	32.5	1.0	0.7	-0.1
Group 4: 30 µg/ animal BNT162b1	Mean	9.16	16.86	96.84	51.16	1.052	20.634
	SD	0.17	1.53	25.92	1.55	0.044	0.238
	N	5	5	5	5	5	5
	%Diff	-1.9	-1.1	9.7	-1.6	-2.4	-0.4

[a] - Anova & Dunnett(Log)
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Rank)

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	8.86	17.98	86.80	52.16	1.068	20.516
100 µg/	SD	0.24	1.51	8.98	1.84	0.036	0.249
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-5.1	5.5	-1.6	0.3	-0.9	-1.0
Group 7:	Mean	8.96	16.30	84.68	51.68	1.064	20.608
100 µg/	SD	0.34	0.65	11.39	2.05	0.050	0.235
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-4.1	-4.4	-4.0	-0.6	-1.3	-0.5

[a] - Anova & Dunnett

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a1]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	7.78	0.757	78.02	11.15	20.82
	SD	0.58	0.105	8.25	0.58	1.26
	N	10	10	10	10	10
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	8.26	0.619*	87.37	11.24	21.90
	SD	0.48	0.097	7.22	0.53	0.92
	N	10	10	10	10	10
	%Diff	6.2	-18.2	12.0	0.8	5.2
Group 3: 10 µg/ animal BNT162a1	Mean	6.92**	0.736	84.49	10.87	23.43**
	SD	0.34	0.150	10.23	0.50	1.16
	N	10	10	10	10	10
	%Diff	-11.1	-2.8	8.3	-2.5	12.5
Group 4: 30 µg/ animal BNT162b1	Mean	7.85	0.770	80.95	11.85	21.46
	SD	0.63	0.099	6.60	0.64	0.88
	N	10	10	10	10	10
	%Diff	0.9	1.7	3.8	6.3	3.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	7.15*	0.748	84.37	11.61	23.80**
100 µg/	SD	0.36	0.088	8.93	0.82	0.78
animal	N	10	10	10	10	10
BNT162b1	%Diff	-8.1	-1.2	8.1	4.1	14.3
Group 6:	Mean	7.19*	0.716	86.49	11.37	23.28**
30 µg/	SD	0.41	0.089	8.46	0.50	0.97
animal	N	10	10	10	10	10
BNT162c1	%Diff	-7.6	-5.4	10.9	2.0	11.8
Group 7:	Mean	7.25	0.733	82.59	11.26	23.91**
100 µg/	SD	0.47	0.095	9.77	0.81	1.04
animal	N	10	10	10	10	10
BNT162b2	%Diff	-6.8	-3.2	5.9	1.0	14.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.64 n	0.484 n	99.52 n	12.17 n	23.57 n
	SD	1.01	0.107	4.66	0.80	0.79
	N	10	10	10	10	10
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a1]	PDW (%) [a2]	RDW (%) [a1]	MPC (g/dL) [a1]
Group 1: Control	Mean	10.78	1.156	56.63	14.25	17.77
	SD	0.48	0.177	1.84	0.60	1.01
	N	10	10	10	10	10
	-					
Group 2: 30 µg/ animal BNT162a1	Mean	11.93	0.733**	68.54**	15.83**	19.72**
	SD	1.22	0.153	5.88	0.73	0.85
	N	10	10	10	10	10
	%Diff	10.7	-36.6	21.0	11.1	11.0
Group 3: 10 µg/ animal BNT162a1	Mean	8.93**	0.619**	82.72**	13.01**	20.34**
	SD	0.97	0.135	6.86	0.66	0.86
	N	10	10	10	10	10
	%Diff	-17.2	-46.5	46.1	-8.7	14.5
Group 4: 30 µg/ animal BNT162b1	Mean	10.55	0.924**	61.27	15.12*	19.33**
	SD	0.56	0.134	4.66	0.62	1.00
	N	10	10	10	10	10
	%Diff	-2.1	-20.1	8.2	6.1	8.8

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	9.34**	0.654**	84.26**	13.30*	21.36**
100 µg/	SD	0.78	0.100	7.72	0.80	0.96
animal	N	10	10	10	10	10
BNT162b1	%Diff	-13.4	-43.4	48.8	-6.7	20.2
Group 7:	Mean	9.53**	0.657**	80.65**	13.37*	21.02**
100 µg/	SD	1.16	0.103	6.96	0.78	0.96
animal	N	10	10	10	10	10
BNT162b2	%Diff	-11.6	-43.2	42.4	-6.2	18.3

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	7.98 n	0.816 n	72.20 n	12.96 n	20.76 n
	SD	0.61	0.084	10.98	0.31	0.91
	N	5	5	5	5	5
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	8.50	0.802	66.30	11.64	18.32
	SD	0.49	0.203	5.37	0.55	0.64
	N	5	5	5	5	5
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	8.44	0.788	66.86	13.38**	18.90
	SD	0.53	0.086	5.43	0.54	0.93
	N	5	5	5	5	5
	%Diff	-0.7	-1.7	0.8	14.9	3.2
Group 3: 10 µg/ animal BNT162a1	Mean	8.08	0.798	72.26	13.14**	20.06*
	SD	0.75	0.123	4.94	0.84	0.59
	N	5	5	5	5	5
	%Diff	-4.9	-0.5	9.0	12.9	9.5
Group 4: 30 µg/ animal BNT162b1	Mean	8.66	0.714	73.16	13.08**	19.48
	SD	0.71	0.104	3.43	0.36	0.55
	N	5	5	5	5	5
	%Diff	1.9	-11.0	10.3	12.4	6.3

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	7.74	0.692	71.88	13.36**	20.64**
100 µg/	SD	0.38	0.106	11.82	0.23	1.61
animal	N	5	5	5	5	5
BNT162b1	%Diff	-8.9	-13.7	8.4	14.8	12.7
Group 7:	Mean	7.76	0.780	72.34	13.36**	20.96**
100 µg/	SD	0.54	0.146	4.02	0.30	0.86
animal	N	5	5	5	5	5
BNT162b2	%Diff	-8.7	-2.7	9.1	14.8	14.4

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Reticulocyte (Relative)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	2	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Reticulocyte (Relative)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	4	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	HCT	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	5	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	WBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	PLT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	HCT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Reticulocyte (Relative)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	Reticulocyte (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Reticulocyte (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	3	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Reticulocyte (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	4	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	WBC	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	31	6	Male	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	PLT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	HCT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Basophils (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Lymphocytes (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Lymphocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	Monocytes (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	17	2	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Eosinophils (Absolute)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	5	Male	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Monocytes (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Male	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	MCHC	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	aPTT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Fibrinogen	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	MCV	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Male	aPTT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Fibrinogen	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Fibrinogen	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	MCV	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	aPTT	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	31	6	Male	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	MPC	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	MPC	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	5	Male	Platlet Dist Width	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Platlet Dist Width	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	4	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	38	2	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	4	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	7	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	WBC	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Reticulocyte (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	PLT	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Reticulocyte (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Reticulocyte (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	5	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	WBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	PLT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	HCT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	RBC	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Female	WBC	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Female	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	PLT	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	WBC	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	PLT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	HCT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Monocytes (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Basophils (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	10	6	Female	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	Monocytes (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	2	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	Basophils (Absolute)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Monocytes (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Eosinophils (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	3	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Basophils (Absolute)	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	4	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Female	Monocytes (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Eosinophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Basophils (Absolute)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Basophils (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	3	Female	MCHC	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	6	Female	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	MCHC	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Female	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Fibrinogen	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Fibrinogen	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	3	Female	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Fibrinogen	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	MCHC	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MCHC	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	MCV	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Plateletcrit	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	3	Female	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	MPV	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	MPV	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	MPV	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	RDW	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	RDW	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	RDW	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	38	2	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	MPC	*	Anova & Dunnett: * = p ≤ 0.05
	38	4	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	38	7	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	7	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
1	8.4	7.25	7.49	4.2	307.3	973	41.2
2	8.5	6.94	9.22	4.1	286.2	871	40.9
3	8.9	7.45	8.28	5.0	374.2	1090	43.7
4	8.7	7.25	7.25	4.3	311.9	894	42.2
5	8.5	7.61	14.48	4.2	323.2	1017	41.3
11	8.9	7.82	9.07	4.0	316.0	896	43.3
12	8.2	6.51	9.33	5.2	337.1	1124	40.2
13	8.4	7.24	11.08	3.9	283.5	1050	40.9
14	8.9	7.48	8.86	3.1	234.5	1237	43.3
15	8.6	7.15	8.61	4.1	295.7	833	42.2
Mean	8.60	7.270	9.367	4.21	306.96	998.5	41.92
SD	0.24	0.365	2.087	0.58	36.75	129.0	1.21
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
31	8.6	7.29	15.65	1.3	93.2	1254	41.6
32	8.7	7.69	8.76	0.6	47.3	1191	41.7
33	7.8	6.76	7.69	1.3	91.1	976	36.8
34	8.4	7.35	11.30	1.1	81.6	982	40.1
35	8.3	7.17	12.35	0.9	67.4	1105	40.4
41	8.5	6.88	11.97	1.1	74.0	1089	40.5
42	8.6	7.24	12.14	0.8	54.7	941	40.8
43	8.4	7.16	15.07	1.1	81.6	888	41.1
44	8.5	7.39	12.72	1.1	80.0	915	41.5
45	8.5	7.25	9.81	1.1	77.6	876	41.3
Mean	8.43	7.218	11.746	1.04	74.85	1021.7	40.58
SD	0.25	0.260	2.519	0.22	14.71	131.1	1.44
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
61	8.9	7.83	9.50	1.2	95.7	1077	43.1
62	8.5	7.57	8.92	1.6	120.2	1453	41.5
63	8.9	7.76	8.64	1.5	112.8	970	41.7
64	9.3	8.14	14.66	0.7	60.8	905	43.9
65	9.0	7.43	9.12	1.9	139.7	1057	42.4
71	8.4	7.05	11.26	1.7	122.2	1219	39.9
72	9.1	7.88	9.98	1.6	122.3	1116	43.0
73	9.9	8.37	11.06	1.6	132.8	1134	47.4
74	9.1	7.92	12.29	1.5	116.6	1032	43.6
75	8.8	7.59	10.31	1.8	139.7	1223	41.2
Mean	8.99	7.754	10.574	1.51	116.28	1118.6	42.77
SD	0.42	0.371	1.841	0.34	23.50	154.1	2.03
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
91	8.2	7.16	10.05	1.9	137.5	898	40.3
92	8.2	7.12	9.23	2.3	160.9	954	40.7
93	8.3	7.31	10.32	2.8	207.2	1035	39.8
94	8.2	7.29	13.56	1.7	123.7	1200	40.4
95	8.3	7.03	12.80	2.9	206.5	993	40.8
101	8.4	7.16	11.85	2.0	146.3	823	41.0
102	8.1	7.00	7.73	2.5	178.0	1216	40.5
103	7.8	6.81	7.64	2.6	174.1	987	38.7
104	8.3	7.47	9.37	2.6	192.7	888	40.8
105	8.3	6.91	7.46	2.7	184.3	1022	40.9
Mean	8.21	7.126	10.001	2.40	171.12	1001.6	40.39
SD	0.17	0.198	2.166	0.41	28.57	126.9	0.69
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
121	8.9	7.84	12.00	2.1	161.6	902	42.4
122	8.9	7.83	7.14	1.0	76.7	1124	42.3
123	8.5	7.39	13.99	1.7	125.7	1224	41.3
124	8.9	7.54	10.67	1.7	125.7	829	41.9
125	9.2	8.04	9.78	1.5	120.8	1223	44.2
131	9.1	7.69	15.07	1.1	86.1	1182	42.6
132	9.3	8.25	8.29	1.2	100.8	852	45.0
133	8.9	7.82	10.37	1.1	89.0	1060	41.9
134	8.8	7.86	11.47	1.7	136.5	1014	41.7
135	8.8	7.58	10.33	1.4	102.5	1106	42.0
Mean	8.93	7.784	10.911	1.45	112.54	1051.6	42.53
SD	0.23	0.249	2.388	0.35	26.19	148.2	1.17
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
151	9.4	8.06	11.80	1.1	91.8	1060	44.5
152	9.4	7.89	15.19	0.9	71.8	953	44.2
153	8.7	7.68	14.61	0.4	32.0	1008	41.6
154	8.9	7.55	11.33	1.1	85.3	965	41.9
155	8.8	7.59	16.77	1.3	95.2	1212	43.1
161	8.4	7.36	11.35	1.0	74.4	1292	40.4
162	8.6	7.41	9.97	0.9	64.7	1251	41.6
163	8.9	7.97	12.72	1.4	107.6	920	42.3
164	9.2	8.29	13.44	0.8	70.1	1293	43.5
165	9.2	8.16	11.68	1.0	77.7	1039	43.5
Mean	8.95	7.796	12.886	0.99	77.06	1099.3	42.66
SD	0.34	0.323	2.098	0.28	20.59	147.4	1.31
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
181	8.8	7.97	10.79	1.3	101.3	832	41.7
182	8.8	7.42	13.27	1.2	90.5	1033	42.3
183	8.9	7.77	14.25	1.1	89.2	940	42.3
184	9.2	7.73	12.92	1.3	98.0	841	43.4
185	9.4	8.00	10.95	1.4	113.6	994	44.1
191	9.1	7.87	11.76	0.9	71.7	876	42.3
192	9.3	7.97	14.38	0.7	59.3	698	43.0
193	9.2	7.88	12.73	1.1	86.5	955	44.0
194	9.1	7.82	12.30	0.9	70.2	1322	42.0
195	9.3	8.05	14.99	0.9	74.9	998	43.7
Mean	9.11	7.848	12.834	1.08	85.52	948.9	42.88
SD	0.21	0.182	1.431	0.23	16.53	164.8	0.87
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
151	8.9	7.72	13.54	2.4	187.4	643	42.1
152	9.1 I	7.80 I	29.53 I	2.9 I	229.1 I	751 I	43.3 I
153	8.7	7.67	21.69	2.5	189.1	745	41.4
154	8.8	7.78	16.88	3.2	249.3	691	42.5
155	8.5	7.35	23.33	2.7	197.2	887	41.7
156	8.6	7.58	17.76	3.0	229.6	741	40.4
157	8.4	7.62	19.12	2.5	194.3	580	39.6
158	9.3	8.43	17.78	1.9	159.8	537	44.3
159	8.1	7.26	18.15	2.2	162.2	743	37.6
160	9.1	7.87	23.37	1.6	128.7	770	41.7
Mean	8.75	7.708	20.115	2.49	192.67	708.8	41.46
SD	0.37	0.319	4.492	0.50	36.61	100.9	1.90
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
1	9.0	8.01	8.28	3.1	247.1	1176	44.9
2	9.3	7.94	7.33	2.8	222.4	792	46.2
3	9.3	8.00	6.21	3.1	245.1	1391	46.7
4	9.0	7.89	8.21	2.6	202.4	958	43.7
5	8.8	8.12	10.65	2.9	234.1	1264	43.8
6	9.2	7.83	8.48	3.5	271.6	900	45.0
7	9.5	8.28	14.28	3.0	251.7	1065	45.6
8	9.3	7.84	9.22	3.1	241.7	878	46.1
9	8.7	7.45	11.36	3.3	246.5	1217	43.0
10	9.3	8.20	6.88	2.2	183.4	1251	45.3
Mean	9.14	7.956	9.090	2.96	234.60	1089.2	45.03
SD	0.25	0.232	2.418	0.37	25.66	199.5	1.21
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
31	9.3	8.19	22.02	2.5	203.4	959	45.8
32	8.4	7.69	10.09	2.4	184.9	867	41.9
33	8.4	7.48	12.18	2.5	189.9	716	41.3
34	8.2	7.44	20.51	1.6	121.1	778	39.9
35	8.7	7.66	15.07	2.9	219.3	1029	41.8
36	8.6	7.50	14.89	2.9	216.0	855	42.8
37	8.8	7.77	15.55	1.8	142.8	805	42.7
38	8.7	7.72	16.89	2.3	176.0	641	42.7
39	8.7	7.87	16.42	1.8	140.8	525	42.7
40	8.9	7.91	19.18	1.9	154.1	872	42.7
Mean	8.67	7.723	16.280	2.26	174.83	804.7	42.43
SD	0.31	0.229	3.632	0.46	33.86	148.6	1.50
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
61	9.2	8.38	16.81	2.2	180.5	708	43.9
62	8.3	7.55	12.08	2.8	211.1	1226	40.1
63	8.8	8.15	14.49	1.7	136.7	668	41.2
64	8.8	7.98	16.23	2.1	167.8	757	42.1
65	8.5	7.43	10.46	3.0	225.4	872	40.0
66	8.8	8.07	13.49	2.5	203.2	631	41.3
67	8.9	7.91	16.34	2.4	189.0	691	42.1
68	8.9	8.31	15.88	2.8	234.1	818	41.4
69	8.5	7.33	17.27	2.6	192.7	845	39.7
70	8.2	7.33	14.54	2.2	163.4	835	39.2
Mean	8.69	7.844	14.759	2.43	190.39	805.1	41.10
SD	0.31	0.403	2.207	0.39	29.73	169.4	1.40
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
91	8.5	7.72	16.45	2.1	161.0	885	42.3
92	8.6	7.78	11.90	2.1	161.4	876	43.1
93	8.6	7.77	13.19	2.9	221.5	874	42.5
94	8.5	7.78	16.64	2.5	193.6	1320	42.3
95	8.3	7.34	17.38	2.8	202.5	887	40.9
96	8.9	7.87	22.80	2.4	185.6	908	43.3
97	8.8	7.76	12.77	2.8	217.3	1071	42.9
98	8.3	7.25	12.84	2.5	179.0	800	40.7
99	8.9	8.02	9.00	2.2	177.7	703	45.1
100	8.8	8.22	13.15	2.3	186.5	982	43.5
Mean	8.62	7.751	14.612	2.46	188.61	930.6	42.66
SD	0.23	0.285	3.826	0.30	20.68	167.8	1.27
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
121	7.8	7.25	15.87	3.8	278.9	628	37.3
122	8.2	7.67	14.02	3.5	269.2	664	39.3
123	7.7	6.81	19.41	2.8	190.0	1022	36.7
124	7.9	7.12	15.26	2.5	176.2	947	37.8
125	8.2	7.44	17.07	4.1	301.6	877	38.7
126	7.8	7.17	26.77	4.3	311.3	736	36.0
127	8.6	7.87	12.80	2.3	180.2	984	41.0
128	8.5	8.02	14.18	2.4	190.1	716	40.6
129	8.6	8.15	19.16	1.9	155.0	688	41.0
130	8.1	7.61	11.10	2.4	180.4	910	39.5
Mean	8.14	7.511	16.564	3.00	223.29	817.2	38.79
SD	0.34	0.430	4.442	0.85	59.50	145.9	1.80
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
181	8.0	7.56	16.36	2.5	190.8	753	37.9
182	8.1	7.17	14.77	2.7	193.4	801	38.8
183	8.3	7.69	25.89	1.7	132.9	658	40.0
184	8.7	7.78	22.53	1.7	130.1	734	41.3
185	8.9	8.02	22.85	2.0	162.7	739	42.5
186	8.2	7.62	14.24	2.9	220.5	579	38.4
187	8.5	8.09	20.86	2.4	190.3	849	40.1
188	8.5	8.00	16.24	2.1	166.8	1020	40.9
189	8.0	7.40	15.99	2.1	152.9	720	38.4
190	7.9	7.37	29.03	2.6	189.0	861	38.2
Mean	8.31	7.670	19.876	2.27	172.94	771.4	39.65
SD	0.33	0.307	5.114	0.41	28.95	121.1	1.55
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
161	8.7	8.31	8.76	2.6	214.5	1017	41.9
162	8.9	8.35	6.48	2.1	171.5	1117	42.9
163	8.6	8.28	7.67	2.3	193.4	856	41.3
164	8.8	8.73	4.84	2.2	188.6	854	43.6
165	9.0	8.61	6.75	2.8	242.3	1043	43.4
Mean	8.80	8.456	6.900	2.40	202.06	977.4	42.62
SD	0.16	0.201	1.457	0.29	27.22	117.6	0.99
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
11	9.5	9.39	10.47	2.4	225.8	1155	46.3
12	8.6	7.85	9.83	3.4	270.5	940	42.6
13	8.4	8.04	14.52	3.4	270.9	982	42.3
14	9.3	8.88	8.13	2.8	244.4	1115	45.7
15	9.0	8.46	7.68	2.0	169.0	750	44.2
Mean	8.96	8.524	10.126	2.80	236.12	988.4	44.22
SD	0.46	0.626	2.715	0.62	42.05	160.5	1.79
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
41	9.1	8.46	8.92	3.1	264.4	1096	44.4
42	8.7	8.61	7.46	3.4	291.1	1174	43.7
43	8.9	8.50	10.36	2.8	239.5	1161	43.7
44	9.1	8.80	11.26	2.6	226.0	1012	44.6
45	9.2	8.54	8.27	3.3	284.3	1089	45.3
Mean	9.00	8.582	9.254	3.04	261.06	1106.4	44.34
SD	0.20	0.134	1.545	0.34	28.05	64.9	0.67
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
71	8.8	8.19	13.08	3.2	259.3	1227	42.5
72	9.4	9.25	7.55	2.5	235.3	871	45.5
73	9.6	9.11	7.95	2.1	190.5	813	46.9
74	8.9	8.61	10.20	2.5	219.3	1136	44.1
75	8.5	8.24	7.62	2.5	205.9	1153	42.3
Mean	9.04	8.680	9.280	2.56	222.06	1040.0	44.26
SD	0.45	0.487	2.388	0.40	26.58	185.1	1.97
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
101	8.7	8.56	9.70	2.8	243.6	924	42.5
102	8.7	8.53	5.07	2.0	174.0	865	43.2
103	8.1	7.76	8.31	2.9	226.1	1088	39.7
104	8.8	8.88	10.89	2.2	193.1	785	44.4
105	8.5	7.96	6.36	3.4	273.6	1048	42.8
Mean	8.56	8.338	8.066	2.66	222.08	942.0	42.52
SD	0.28	0.463	2.376	0.56	39.64	126.0	1.73
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
131	8.9	8.64	10.03	2.0	169.5	998	44.1
132	9.1	8.84	7.31	2.3	204.3	826	44.6
133	8.5	8.40	10.12	2.2	186.9	994	41.1
134	9.1	8.97	8.60	3.0	270.1	922	45.4
135	8.7	8.49	9.18	2.1	175.2	867	42.6
Mean	8.86	8.668	9.048	2.32	201.20	921.4	43.56
SD	0.26	0.237	1.157	0.40	40.75	76.2	1.71
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
191	9.1	8.99	8.87	2.6	231.3	929	45.2
192	9.3	9.31	12.64	2.5	229.2	1100	45.7
193	8.6	8.37	9.54	2.7	226.4	1081	41.7
194	9.2	8.74	7.19	1.6	142.1	1217	44.6
195	9.2	9.01	13.61	2.6	229.9	808	45.6
Mean	9.08	8.884	10.370	2.40	211.78	1027.0	44.56
SD	0.28	0.351	2.679	0.45	38.99	159.6	1.66
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
1	13.7	80.8	3.0	1.5	0.8	0.3
2	18.9	74.7	3.8	1.5	0.8	0.2
3	14.5	80.5	2.4	1.1	1.2	0.3
4	20.8	72.1	3.2	1.7	2.0	0.2
5	17.6	77.1	3.1	1.0	0.8	0.4
11	16.9	77.1	3.2	1.9	0.7	0.2
12	16.7	77.7	3.1	1.5	0.7	0.2
13	15.5	77.7	4.1	1.4	0.9	0.4
14	12.2	83.6	2.1	0.7	1.1	0.3
15	12.5	82.6	3.0	0.8	0.8	0.3
Mean	15.93	78.39	3.10	1.31	0.98	0.28
SD	2.78	3.54	0.58	0.39	0.39	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
31	25.6	65.2	2.8	0.6	5.4	0.4
32	29.7	64.8	2.5	0.7	2.1	0.3
33	25.5	67.2	2.4	1.3	3.5	0.2
34	29.1	59.1	3.4	1.4	6.7	0.3
35	34.6	55.4	2.5	1.0	6.1	0.4
41	27.7	56.5	4.5	1.4	9.5	0.4
42	35.0	52.4	4.4	0.8	7.1	0.4
43	29.1	60.3	4.2	1.5	4.5	0.4
44	30.9	57.6	3.8	1.0	6.4	0.3
45	23.3	68.9	3.7	0.7	3.3	0.2
Mean	29.05	60.74	3.42	1.04	5.46	0.33
SD	3.79	5.51	0.82	0.34	2.17	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
61	12.8	80.9	3.0	1.0	1.7	0.5
62	14.8	78.1	2.5	1.3	2.9	0.4
63	19.1	74.0	2.8	1.7	1.9	0.5
64	15.1	77.5	3.3	1.2	2.3	0.6
65	19.1	72.2	4.0	1.6	2.7	0.4
71	9.7	85.4	2.2	0.5	1.7	0.5
72	12.3	79.9	3.4	0.7	3.4	0.3
73	9.8	85.1	2.1	0.9	1.7	0.5
74	10.4	84.8	2.3	0.9	1.2	0.4
75	12.7	81.3	2.4	1.6	1.6	0.3
Mean	13.58	79.92	2.80	1.14	2.11	0.44
SD	3.45	4.56	0.62	0.41	0.69	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
91	12.6	80.5	3.0	1.5	2.1	0.3
92	10.6	85.3	2.1	0.7	1.0	0.3
93	12.0	82.0	3.0	0.9	1.6	0.4
94	16.0	78.6	2.0	0.5	2.4	0.4
95	12.2	83.0	2.0	1.1	1.4	0.4
101	17.7	76.7	3.3	1.2	0.8	0.4
102	20.5	73.4	2.2	2.5	1.1	0.3
103	13.4	79.8	2.9	2.0	1.7	0.2
104	13.6	80.9	2.5	1.5	1.2	0.3
105	19.2	75.5	2.7	1.3	1.0	0.3
Mean	14.78	79.57	2.57	1.32	1.43	0.33
SD	3.37	3.61	0.48	0.60	0.52	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
121	12.8	81.6	1.7	1.2	2.3	0.5
122	13.2	81.5	2.1	1.5	1.5	0.3
123	11.4	83.2	1.7	0.7	2.5	0.5
124	15.6	76.7	3.0	1.4	2.8	0.5
125	9.2	87.2	1.0	1.0	1.4	0.2
131	12.4	81.9	2.3	1.7	1.2	0.4
132	12.0	80.2	2.2	0.5	4.6	0.4
133	10.5	85.1	1.7	0.8	1.7	0.2
134	10.6	85.1	1.6	1.1	1.2	0.5
135	13.1	81.5	2.0	1.1	1.9	0.4
Mean	12.08	82.40	1.93	1.10	2.11	0.39
SD	1.79	2.95	0.53	0.37	1.03	0.12
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
151	16.2	76.7	3.7	0.9	2.1	0.4
152	21.7	69.0	5.2	0.6	3.0	0.6
153	20.2	73.8	1.7	0.6	3.3	0.5
154	21.5	65.9	3.7	0.5	8.0	0.3
155	17.5	75.5	2.3	0.8	3.3	0.6
161	19.7	72.3	4.2	1.2	2.2	0.4
162	22.8	70.7	3.0	0.9	2.2	0.4
163	22.0	71.4	2.4	0.9	2.8	0.4
164	19.3	74.9	2.2	0.4	2.6	0.5
165	15.5	77.8	3.4	0.7	2.2	0.4
Mean	19.64	72.80	3.18	0.75	3.17	0.45
SD	2.52	3.68	1.07	0.24	1.76	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
181	20.6	73.4	1.7	0.9	2.9	0.5
182	6.5	89.7	1.2	0.3	1.8	0.5
183	14.0	80.0	1.6	0.6	3.3	0.5
184	15.2	78.0	2.0	1.2	3.1	0.5
185	10.6	83.8	2.0	0.6	2.5	0.5
191	28.0	62.9	2.9	1.5	4.4	0.3
192	19.2	73.4	2.5	1.7	2.7	0.5
193	20.2	73.0	3.2	0.6	2.4	0.6
194	15.0	78.8	2.4	0.7	2.6	0.5
195	8.6	86.5	2.0	0.5	1.9	0.5
Mean	15.79	77.95	2.15	0.86	2.76	0.49
SD	6.43	7.77	0.61	0.46	0.75	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
151	49.4	41.1	2.2	0.4	6.6	0.3
152	38.6 I	53.4 I	3.6 I	0.5 I	2.9 I	1.0 I
153	50.2	40.5	1.5	0.6	6.8	0.4
154	39.6	43.3	5.2	0.4	11.2	0.4
155	38.4	50.2	2.2	0.3	8.5	0.4
156	43.5	45.6	3.6	0.5	6.4	0.2
157	55.8	28.8	3.8	0.8	10.5	0.4
158	53.4	36.4	3.2	0.3	6.3	0.4
159	39.6	46.7	3.8	0.7	8.6	0.6
160	35.2	57.3	2.7	0.3	4.0	0.6
Mean	44.37	44.33	3.18	0.48	7.18	0.47
SD	7.23	8.32	1.06	0.18	2.61	0.22
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
1	12.5	81.3	3.5	1.3	1.1	0.2
2	23.4	70.7	3.4	1.6	0.6	0.3
3	14.4	78.1	4.5	1.8	1.0	0.2
4	19.5	74.1	3.2	1.6	1.2	0.3
5	29.4	64.7	4.0	0.8	0.8	0.3
6	9.8	85.6	2.1	1.3	1.0	0.3
7	13.5	80.1	3.6	0.8	1.5	0.5
8	16.7	78.0	3.2	1.0	0.8	0.4
9	8.7	85.7	3.1	1.1	0.9	0.4
10	13.2	81.3	3.2	1.4	0.6	0.3
Mean	16.11	77.96	3.38	1.27	0.95	0.32
SD	6.39	6.57	0.63	0.34	0.28	0.09
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
31	44.9	41.2	2.9	0.5	10.1	0.5
32	46.7	47.8	3.0	0.5	1.8	0.3
33	47.1	44.7	4.0	0.7	3.2	0.3
34	53.3	34.0	4.8	0.9	6.5	0.5
35	45.3	41.6	3.8	0.6	8.2	0.3
36	53.4	35.8	3.2	0.7	6.7	0.2
37	50.4	42.7	3.1	0.8	2.7	0.4
38	48.2	37.1	3.2	0.6	10.6	0.3
39	48.6	39.1	3.0	0.4	8.5	0.3
40	38.4	48.0	3.7	0.4	9.0	0.6
Mean	47.63	41.20	3.47	0.61	6.73	0.37
SD	4.39	4.79	0.60	0.17	3.16	0.13
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
61	34.5	54.9	5.2	0.4	4.4	0.6
62	46.3	46.3	1.8	0.9	4.3	0.4
63	37.2	54.0	4.4	0.7	3.1	0.5
64	38.4	53.0	5.2	0.8	2.3	0.5
65	33.8	57.2	5.2	1.5	1.8	0.4
66	43.6	49.9	2.0	0.6	3.3	0.6
67	34.7	57.0	4.1	0.8	3.1	0.4
68	36.5	54.8	4.0	0.4	3.9	0.4
69	30.4	58.2	5.6	0.8	4.6	0.4
70	30.2	62.9	4.3	0.6	1.7	0.4
Mean	36.56	54.82	4.18	0.75	3.25	0.46
SD	5.18	4.57	1.32	0.31	1.06	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
91	43.6	46.9	6.0	1.3	1.8	0.4
92	35.6	56.3	5.1	1.6	1.1	0.4
93	40.1	50.7	5.5	1.6	1.7	0.4
94	48.8	45.4	2.5	1.5	1.5	0.3
95	41.6	50.3	4.5	1.8	1.4	0.4
96	34.2	58.1	4.0	1.2	1.9	0.7
97	30.9	62.1	3.1	1.4	2.2	0.3
98	48.7	45.8	2.1	1.5	1.5	0.3
99	48.6	41.3	5.9	2.2	1.7	0.4
100	34.3	56.9	4.8	2.3	1.3	0.5
Mean	40.64	51.38	4.35	1.64	1.61	0.41
SD	6.72	6.71	1.39	0.36	0.32	0.12
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
121	48.2	42.7	3.1	2.6	3.1	0.3
122	53.8	35.6	3.7	3.4	3.1	0.4
123	47.2	43.5	3.8	1.7	3.3	0.5
124	43.0	47.3	5.0	2.4	1.9	0.4
125	49.3	41.6	3.8	2.7	2.3	0.3
126	58.8	28.9	2.9	2.1	6.8	0.4
127	39.1	52.2	3.6	1.7	3.1	0.4
128	47.9	43.4	3.7	1.3	3.4	0.3
129	46.8	45.8	1.9	1.6	3.5	0.4
130	35.3	57.2	1.9	2.6	2.7	0.3
Mean	46.94	43.82	3.34	2.21	3.32	0.37
SD	6.74	7.90	0.94	0.64	1.32	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
181	58.6	32.4	3.3	2.2	3.3	0.2
182	46.6	48.2	0.9	2.4	1.7	0.2
183	49.6	39.9	3.4	3.1	3.5	0.4
184	54.0	35.3	1.6	3.1	5.6	0.4
185	50.3	41.4	1.2	3.0	3.5	0.6
186	53.0	40.2	2.7	1.8	2.0	0.2
187	54.4	35.6	3.6	3.7	2.5	0.3
188	53.2	38.9	2.9	2.6	2.1	0.4
189	49.5	40.7	3.3	4.1	2.1	0.3
190	49.9	39.2	2.4	2.3	5.8	0.4
Mean	51.91	39.18	2.53	2.83	3.21	0.34
SD	3.40	4.27	0.98	0.71	1.46	0.13
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
161	23.7	69.9	3.6	1.5	1.0	0.3
162	22.7	72.4	2.6	1.5	0.5	0.2
163	21.0	73.1	3.3	1.7	0.9	0.1
164	20.0	73.4	3.7	1.7	0.9	0.3
165	18.1	77.1	2.5	1.3	0.8	0.2
Mean	21.10	73.18	3.14	1.54	0.82	0.22
SD	2.21	2.59	0.56	0.17	0.19	0.08
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
11	18.0	75.1	3.6	2.0	1.1	0.3
12	13.0	80.9	3.0	1.9	0.9	0.3
13	20.9	70.7	4.6	2.6	1.0	0.3
14	18.5	76.2	2.7	0.9	1.5	0.2
15	17.3	77.2	2.7	1.5	0.9	0.3
Mean	17.54	76.02	3.32	1.78	1.08	0.28
SD	2.88	3.69	0.80	0.63	0.25	0.04
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
41	14.1	78.7	3.5	2.2	1.2	0.2
42	18.9	76.0	2.9	1.2	0.9	0.2
43	14.2	77.2	5.0	1.3	2.0	0.3
44	16.0	76.9	3.6	1.7	1.4	0.4
45	13.1	80.1	3.7	1.0	1.8	0.4
Mean	15.26	77.78	3.74	1.48	1.46	0.30
SD	2.29	1.62	0.77	0.48	0.44	0.10
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
71	10.8	84.7	2.1	0.9	1.2	0.3
72	19.7	73.7	4.4	1.2	0.8	0.2
73	17.5	76.4	3.1	2.1	0.7	0.2
74	16.2	78.3	2.9	1.4	0.9	0.2
75	14.5	79.8	2.4	2.1	1.0	0.1
Mean	15.74	78.58	2.98	1.54	0.92	0.20
SD	3.35	4.11	0.89	0.54	0.19	0.07
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
101	21.6	70.8	4.7	1.7	0.9	0.3
102	28.3	65.7	3.3	1.9	0.6	0.2
103	13.9	78.2	4.1	2.6	1.0	0.3
104	15.1	79.0	2.5	2.0	1.1	0.3
105	20.8	72.7	3.1	1.9	1.4	0.2
Mean	19.94	73.28	3.54	2.02	1.00	0.26
SD	5.77	5.50	0.86	0.34	0.29	0.05
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
131	25.6	68.3	2.3	2.8	0.7	0.4
132	20.1	74.6	3.2	0.9	0.9	0.2
133	14.6	79.8	2.3	1.7	1.2	0.3
134	18.8	76.3	2.3	1.6	0.8	0.2
135	20.2	75.1	2.5	1.4	0.7	0.1
Mean	19.86	74.82	2.52	1.68	0.86	0.24
SD	3.93	4.17	0.39	0.70	0.21	0.11
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
191	28.5	64.7	3.9	2.1	0.6	0.3
192	15.5	78.2	2.1	2.4	1.5	0.3
193	20.2	72.9	4.0	1.8	0.8	0.3
194	11.3	82.3	3.0	1.6	1.6	0.2
195	14.2	81.1	2.5	0.9	1.0	0.3
Mean	17.94	75.84	3.10	1.76	1.10	0.28
SD	6.72	7.21	0.84	0.57	0.44	0.04
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
1	1.03	6.05	0.22	0.11	0.06	0.02
2	1.74	6.89	0.35	0.14	0.08	0.02
3	1.20	6.67	0.20	0.09	0.10	0.02
4	1.51	5.23	0.23	0.13	0.14	0.01
5	2.55	11.17	0.45	0.15	0.11	0.05
11	1.53	6.99	0.29	0.17	0.06	0.02
12	1.56	7.25	0.29	0.14	0.07	0.02
13	1.72	8.62	0.45	0.15	0.10	0.04
14	1.08	7.40	0.18	0.06	0.10	0.03
15	1.07	7.11	0.26	0.07	0.07	0.03
Mean	1.499	7.338	0.292	0.121	0.089	0.026
SD	0.458	1.608	0.097	0.037	0.026	0.012
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
31	4.01	10.21	0.43	0.10	0.84	0.06
32	2.60	5.68	0.22	0.06	0.18	0.02
33	1.96	5.17	0.18	0.10	0.27	0.01
34	3.29	6.68	0.38	0.16	0.76	0.03
35	4.27	6.84	0.31	0.12	0.76	0.05
41	3.32	6.76	0.53	0.17	1.14	0.04
42	4.25	6.36	0.54	0.09	0.86	0.05
43	4.39	9.09	0.63	0.22	0.67	0.06
44	3.93	7.32	0.48	0.13	0.82	0.04
45	2.28	6.76	0.36	0.06	0.33	0.02
Mean	3.430	7.087	0.406	0.121	0.663	0.038
SD	0.888	1.507	0.144	0.051	0.305	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
61	1.22	7.68	0.29	0.10	0.16	0.05
62	1.32	6.96	0.23	0.12	0.26	0.03
63	1.65	6.39	0.24	0.15	0.16	0.04
64	2.22	11.37	0.48	0.17	0.34	0.09
65	1.74	6.58	0.37	0.15	0.24	0.04
71	1.09	9.62	0.25	0.05	0.20	0.05
72	1.23	7.97	0.34	0.07	0.34	0.03
73	1.08	9.41	0.23	0.10	0.18	0.06
74	1.28	10.42	0.28	0.11	0.15	0.05
75	1.31	8.39	0.25	0.17	0.16	0.03
Mean	1.414	8.479	0.296	0.119	0.219	0.047
SD	0.355	1.682	0.080	0.041	0.073	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
91	1.26	8.09	0.30	0.15	0.21	0.03
92	0.98	7.87	0.19	0.06	0.09	0.03
93	1.24	8.46	0.31	0.09	0.16	0.05
94	2.17	10.65	0.28	0.07	0.33	0.06
95	1.57	10.62	0.25	0.14	0.18	0.05
101	2.10	9.09	0.39	0.14	0.09	0.04
102	1.59	5.67	0.17	0.19	0.09	0.02
103	1.02	6.10	0.22	0.16	0.13	0.02
104	1.28	7.58	0.24	0.14	0.11	0.03
105	1.43	5.63	0.20	0.10	0.07	0.02
Mean	1.464	7.976	0.255	0.124	0.146	0.035
SD	0.407	1.830	0.067	0.042	0.079	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
121	1.53	9.79	0.20	0.14	0.28	0.06
122	0.94	5.82	0.15	0.11	0.10	0.02
123	1.60	11.64	0.24	0.09	0.35	0.07
124	1.66	8.18	0.32	0.15	0.30	0.05
125	0.90	8.53	0.10	0.10	0.13	0.02
131	1.88	12.34	0.35	0.25	0.19	0.06
132	1.00	6.65	0.18	0.04	0.38	0.03
133	1.09	8.83	0.17	0.08	0.17	0.02
134	1.21	9.76	0.18	0.12	0.14	0.05
135	1.36	8.42	0.20	0.11	0.20	0.04
Mean	1.317	8.996	0.209	0.119	0.224	0.042
SD	0.340	2.006	0.076	0.055	0.097	0.019
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
151	1.91	9.06	0.44	0.11	0.25	0.05
152	3.29	10.48	0.78	0.10	0.46	0.08
153	2.95	10.77	0.24	0.09	0.48	0.07
154	2.44	7.47	0.42	0.06	0.91	0.04
155	2.93	12.66	0.38	0.14	0.56	0.10
161	2.24	8.20	0.48	0.13	0.25	0.05
162	2.27	7.05	0.30	0.09	0.22	0.04
163	2.80	9.08	0.31	0.12	0.36	0.06
164	2.60	10.07	0.30	0.05	0.35	0.07
165	1.81	9.09	0.40	0.08	0.26	0.04
Mean	2.524	9.393	0.405	0.097	0.410	0.060
SD	0.478	1.671	0.152	0.029	0.210	0.020
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
181	2.23	7.92	0.18	0.10	0.32	0.05
182	0.86	11.91	0.16	0.04	0.24	0.06
183	1.99	11.40	0.22	0.08	0.47	0.08
184	1.97	10.08	0.25	0.15	0.41	0.06
185	1.17	9.17	0.21	0.07	0.27	0.06
191	3.29	7.40	0.34	0.17	0.52	0.04
192	2.76	10.56	0.36	0.24	0.39	0.08
193	2.57	9.29	0.41	0.08	0.30	0.08
194	1.85	9.70	0.30	0.09	0.32	0.06
195	1.29	12.96	0.30	0.08	0.28	0.08
Mean	1.998	10.039	0.273	0.110	0.352	0.065
SD	0.755	1.733	0.082	0.059	0.092	0.014
N	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
151	6.69	5.57	0.30	0.05	0.89	0.04
152	11.39 I	15.78 I	1.07 I	0.13 I	0.86 I	0.31 I
153	10.89	8.79	0.33	0.12	1.47	0.08
154	6.68	7.30	0.87	0.06	1.89	0.07
155	8.97	11.71	0.51	0.07	1.97	0.10
156	7.73	8.11	0.64	0.10	1.14	0.04
157	10.67	5.50	0.74	0.15	2.00	0.07
158	9.50	6.47	0.56	0.05	1.13	0.07
159	7.19	8.48	0.68	0.13	1.56	0.11
160	8.22	13.39	0.62	0.08	0.93	0.13
Mean	8.793	9.110	0.632	0.094	1.384	0.102
SD	1.767	3.446	0.232	0.037	0.455	0.078
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
1	1.04	6.73	0.29	0.11	0.09	0.02
2	1.72	5.18	0.25	0.11	0.04	0.02
3	0.90	4.85	0.28	0.11	0.06	0.02
4	1.60	6.08	0.26	0.14	0.10	0.02
5	3.13	6.89	0.43	0.09	0.08	0.03
6	0.83	7.25	0.18	0.11	0.08	0.03
7	1.92	11.44	0.52	0.11	0.22	0.06
8	1.54	7.19	0.29	0.09	0.07	0.03
9	0.99	9.74	0.36	0.12	0.10	0.05
10	0.91	5.59	0.22	0.10	0.04	0.02
Mean	1.458	7.094	0.308	0.109	0.088	0.030
SD	0.707	2.057	0.102	0.014	0.051	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
31	9.88	9.07	0.64	0.11	2.21	0.10
32	4.71	4.82	0.30	0.05	0.18	0.03
33	5.73	5.44	0.49	0.09	0.38	0.04
34	10.94	6.98	0.99	0.18	1.33	0.09
35	6.83	6.27	0.58	0.10	1.24	0.05
36	7.95	5.34	0.48	0.11	0.99	0.03
37	7.84	6.64	0.48	0.12	0.42	0.07
38	8.13	6.27	0.53	0.11	1.79	0.05
39	7.98	6.42	0.49	0.07	1.40	0.06
40	7.37	9.20	0.71	0.07	1.73	0.11
Mean	7.736	6.645	0.569	0.101	1.167	0.063
SD	1.803	1.466	0.184	0.036	0.672	0.029
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
61	5.81	9.22	0.87	0.07	0.74	0.10
62	5.60	5.59	0.22	0.10	0.52	0.05
63	5.39	7.83	0.64	0.10	0.45	0.08
64	6.22	8.60	0.84	0.13	0.37	0.07
65	3.54	5.99	0.54	0.16	0.19	0.04
66	5.88	6.73	0.27	0.09	0.45	0.08
67	5.66	9.31	0.67	0.13	0.50	0.07
68	5.79	8.69	0.63	0.07	0.63	0.07
69	5.26	10.05	0.97	0.13	0.80	0.07
70	4.38	9.15	0.62	0.08	0.24	0.06
Mean	5.353	8.116	0.627	0.106	0.489	0.069
SD	0.805	1.525	0.241	0.030	0.197	0.017
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
91	7.18	7.71	0.98	0.21	0.30	0.07
92	4.23	6.70	0.60	0.19	0.13	0.05
93	5.28	6.69	0.72	0.20	0.23	0.05
94	8.12	7.55	0.42	0.25	0.24	0.05
95	7.23	8.74	0.77	0.32	0.25	0.06
96	7.80	13.24	0.91	0.26	0.43	0.15
97	3.95	7.93	0.40	0.18	0.28	0.04
98	6.26	5.88	0.27	0.20	0.19	0.04
99	4.37	3.72	0.53	0.20	0.15	0.03
100	4.51	7.48	0.63	0.30	0.17	0.06
Mean	5.893	7.564	0.623	0.231	0.237	0.060
SD	1.610	2.424	0.227	0.049	0.088	0.034
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
121	7.65	6.77	0.49	0.41	0.49	0.05
122	7.55	4.99	0.52	0.47	0.44	0.05
123	9.16	8.44	0.74	0.32	0.65	0.09
124	6.57	7.21	0.77	0.37	0.29	0.06
125	8.42	7.09	0.64	0.47	0.39	0.06
126	15.75	7.75	0.77	0.56	1.83	0.12
127	5.01	6.68	0.46	0.22	0.39	0.05
128	6.79	6.16	0.52	0.18	0.49	0.04
129	8.98	8.77	0.36	0.31	0.67	0.07
130	3.92	6.35	0.21	0.29	0.30	0.04
Mean	7.980	7.021	0.548	0.360	0.594	0.063
SD	3.197	1.113	0.184	0.119	0.453	0.025
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
181	9.59	5.30	0.54	0.35	0.54	0.04
182	6.88	7.11	0.13	0.35	0.26	0.03
183	12.85	10.34	0.89	0.81	0.91	0.10
184	12.17	7.96	0.36	0.70	1.25	0.09
185	11.50	9.46	0.27	0.68	0.79	0.15
186	7.55	5.73	0.39	0.26	0.29	0.03
187	11.35	7.42	0.74	0.76	0.52	0.07
188	8.63	6.31	0.47	0.42	0.34	0.06
189	7.91	6.51	0.53	0.65	0.34	0.05
190	14.48	11.38	0.70	0.68	1.67	0.12
Mean	10.291	7.752	0.502	0.566	0.691	0.074
SD	2.545	2.029	0.230	0.199	0.468	0.040
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
161	2.08	6.13	0.31	0.13	0.08	0.03
162	1.47	4.69	0.17	0.10	0.04	0.01
163	1.61	5.60	0.25	0.13	0.07	0.01
164	0.97	3.55	0.18	0.08	0.05	0.02
165	1.22	5.20	0.17	0.09	0.06	0.01
Mean	1.470	5.034	0.216	0.106	0.060	0.016
SD	0.420	0.984	0.062	0.023	0.016	0.009
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
11	1.88	7.86	0.38	0.21	0.11	0.03
12	1.28	7.95	0.29	0.18	0.09	0.03
13	3.03	10.26	0.66	0.38	0.14	0.05
14	1.51	6.19	0.22	0.08	0.12	0.01
15	1.33	5.93	0.21	0.12	0.07	0.02
Mean	1.806	7.638	0.352	0.194	0.106	0.028
SD	0.724	1.735	0.185	0.116	0.027	0.015
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
41	1.26	7.02	0.31	0.20	0.11	0.02
42	1.41	5.66	0.21	0.09	0.06	0.02
43	1.47	8.00	0.52	0.13	0.21	0.03
44	1.80	8.66	0.41	0.19	0.16	0.04
45	1.08	6.63	0.30	0.08	0.15	0.03
Mean	1.404	7.194	0.350	0.138	0.138	0.028
SD	0.268	1.173	0.119	0.055	0.056	0.008
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
71	1.41	11.07	0.28	0.12	0.16	0.04
72	1.49	5.57	0.33	0.09	0.06	0.01
73	1.39	6.08	0.25	0.16	0.06	0.01
74	1.65	7.99	0.30	0.14	0.09	0.02
75	1.11	6.08	0.18	0.16	0.08	0.01
Mean	1.410	7.358	0.268	0.134	0.090	0.018
SD	0.196	2.272	0.057	0.030	0.041	0.013
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
101	2.09	6.87	0.45	0.16	0.09	0.03
102	1.44	3.33	0.17	0.09	0.03	0.01
103	1.15	6.50	0.34	0.21	0.08	0.02
104	1.65	8.60	0.27	0.22	0.12	0.03
105	1.32	4.62	0.20	0.12	0.09	0.01
Mean	1.530	5.984	0.286	0.160	0.082	0.020
SD	0.362	2.049	0.113	0.056	0.033	0.010
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
131	2.57	6.85	0.23	0.28	0.07	0.04
132	1.47	5.46	0.23	0.07	0.06	0.02
133	1.48	8.08	0.23	0.17	0.12	0.03
134	1.62	6.56	0.20	0.14	0.07	0.01
135	1.85	6.89	0.23	0.13	0.06	0.01
Mean	1.798	6.768	0.224	0.158	0.076	0.022
SD	0.458	0.935	0.013	0.077	0.025	0.013
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
191	2.52	5.74	0.35	0.18	0.05	0.02
192	1.96	9.88	0.27	0.31	0.19	0.04
193	1.93	6.95	0.38	0.18	0.08	0.03
194	0.81	5.92	0.21	0.11	0.12	0.01
195	1.93	11.04	0.34	0.12	0.13	0.05
Mean	1.830	7.906	0.310	0.180	0.114	0.030
SD	0.623	2.412	0.069	0.080	0.053	0.016
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
1	56.8	1.16	20.34
2	58.9	1.22	20.67
3	58.7	1.19	20.28
4	58.2	1.19	20.49
5	54.3	1.11	20.52
11	55.4	1.14	20.62
12	61.8	1.26	20.32
13	56.5	1.17	20.62
14	57.8	1.20	20.66
15	59.0	1.20	20.38
Mean	57.74	1.184	20.490
SD	2.12	0.042	0.150
N	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
31	57.1	1.17	20.57
32	54.2	1.12	20.75
33	54.4	1.15	21.20
34	54.5	1.15	21.05
35	56.4	1.16	20.66
41	58.8	1.23	20.95
42	56.4	1.18	20.98
43	57.4	1.18	20.49
44	56.2	1.16	20.58
45	57.0	1.17	20.59
Mean	56.24	1.167	20.782
SD	1.48	0.028	0.244
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
61	55.0	1.14	20.64
62	54.9	1.12	20.49
63	53.7	1.14	21.28
64	54.0	1.15	21.25
65	57.1	1.21	21.21
71	56.6	1.20	21.13
72	54.6	1.16	21.21
73	56.5	1.18	20.92
74	55.1	1.15	20.90
75	54.4	1.16	21.31
Mean	55.19	1.161	21.034
SD	1.16	0.028	0.286
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
91	56.3	1.15	20.35
92	57.2	1.15	20.15
93	54.4	1.14	20.92
94	55.5	1.13	20.36
95	58.0	1.18	20.38
101	57.3	1.17	20.50
102	57.8	1.16	20.10
103	56.9	1.15	20.20
104	54.6	1.11	20.35
105	59.3	1.20	20.31
Mean	56.73	1.154	20.362
SD	1.55	0.025	0.229
N	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
121	54.1	1.13	20.95
122	54.1	1.14	21.06
123	55.8	1.16	20.71
124	55.5	1.19	21.36
125	55.0	1.15	20.90
131	55.3	1.18	21.42
132	54.6	1.12	20.60
133	53.5	1.13	21.15
134	53.0	1.12	21.20
135	55.4	1.17	21.04
Mean	54.63	1.149	21.039
SD	0.93	0.025	0.261
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
151	55.2	1.17	21.14
152	56.0	1.19	21.22
153	54.2	1.14	20.94
154	55.5	1.18	21.16
155	56.7	1.16	20.51
161	55.0	1.14	20.73
162	56.1	1.16	20.70
163	53.0	1.12	21.11
164	52.5	1.11	21.21
165	53.3	1.13	21.18
Mean	54.75	1.150	20.990
SD	1.44	0.026	0.256
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
181	52.4	1.11	21.18
182	57.1	1.19	20.83
183	54.4	1.15	21.07
184	56.2	1.19	21.14
185	55.1	1.17	21.28
191	53.8	1.15	21.46
192	54.0	1.17	21.65
193	55.8	1.17	20.96
194	53.7	1.16	21.58
195	54.3	1.16	21.37
Mean	54.68	1.162	21.252
SD	1.38	0.023	0.266
N	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
151	10.2	18.6	290.0	54.6	1.15	21.07
152	9.7	17.1	304.0	55.5 I	1.16 I	20.95 I
153	10.1	18.5	326.0	54.0	1.13	20.94
154	10.2	17.2	299.0	54.6	1.14	20.78
155	9.4	18.0	292.0	56.7	1.15	20.37
156	9.5	19.3	327.0	53.4	1.13	21.15
157	10.3	17.4	310.0	51.9	1.10	21.23
158	10.5	18.8	281.0	52.6	1.11	21.05
159	9.7	18.7	275.0	51.7	1.11	21.45
160	9.5	18.9	278.0	53.0	1.15	21.71
Mean	9.91	18.25	298.20	53.80	1.133	21.070
SD	0.39	0.78	18.63	1.59	0.021	0.364
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
1	9.8	14.6	97.9	56.0	1.13	20.16
2	NV !	NV !	NV !	58.1	1.17	20.05
3	9.2	18.6	117.0	58.4	1.17	19.96
4	9.7	15.4	119.0	55.4	1.14	20.62
5	9.3	18.2	107.0	54.0	1.09	20.20
6	9.7	14.3	109.0	57.5	1.17	20.35
7	9.6	14.3	109.0	55.0	1.15	20.83
8	9.4	14.1	99.9	58.7	1.19	20.21
9	9.6	14.2	88.3	57.8	1.17	20.27
10	9.8	14.2	108.0	55.2	1.13	20.54
Mean	9.57	15.32	106.12	56.61	1.151	20.319
SD	0.22	1.79	9.55	1.67	0.029	0.270
N	9	9	9	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
31	8.4	18.0	301.0	55.9	1.14	20.33
32	9.5	16.7	292.0	54.4	1.09	20.02
33	8.8	14.6	339.0	55.3	1.12	20.29
34	10.5	18.5	316.0	53.7	1.11	20.59
35	9.5	18.1	301.0	54.6	1.13	20.69
36	9.5	17.5	335.0	57.2	1.15	20.10
37	9.9	17.9	322.0	54.9	1.13	20.55
38	10.1	19.5	263.0	55.3	1.12	20.28
39	9.4	19.2	326.0	54.3	1.11	20.37
40	9.3	17.0	296.0	54.0	1.12	20.81
Mean	9.49	17.70	309.10	54.96	1.122	20.403
SD	0.60	1.40	23.06	1.03	0.017	0.253
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
61	10.1	19.5	248.0	52.4	1.10	21.07
62	NV !	NV !	NV !	53.2	1.10	20.65
63	9.9	20.9	253.0	50.6	1.08	21.30
64	9.2	17.3	296.0	52.8	1.11	20.94
65	10.1	16.9	271.0	53.9	1.14	21.18
66	9.2	18.3	287.0	51.2	1.09	21.29
67	9.6	17.0	254.0	53.3	1.13	21.20
68	10.1	17.7	308.0	49.8	1.07	21.41
69	9.6	17.5	275.0	54.1	1.16	21.45
70	9.5	17.9	247.0	53.5	1.12	21.04
Mean	9.70	18.11	271.00	52.48	1.110	21.153
SD	0.37	1.31	22.32	1.47	0.028	0.239
N	9	9	9	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
91	9.4	14.5	254.0	54.8	1.10	20.07
92	10.2	15.2	224.0	55.4	1.10	19.89
93	9.7	14.1	267.0	54.7	1.11	20.23
94	9.7	15.3	277.0	54.4	1.09	20.06
95	9.9	14.5	274.0	55.8	1.14	20.37
96	9.5	14.8	298.0	55.1	1.14	20.63
97	9.5	14.8	266.0	55.3	1.14	20.55
98	9.2	14.1	306.0	56.1	1.14	20.39
99	9.4	13.6	270.0	56.2	1.10	19.64
100	9.1	15.0	278.0	52.9	1.07	20.34
Mean	9.56	14.59	271.40	55.07	1.113	20.217
SD	0.33	0.54	22.57	0.97	0.025	0.305
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
121	9.8	16.8	322.0	51.5	1.08	21.02
122	9.4	17.3	304.0	51.2	1.07	20.90
123	9.4	16.3	293.0	53.9	1.13	20.89
124	9.6	16.3	299.0	53.1	1.10	20.78
125	8.8	17.9	320.0	52.0	1.10	21.10
126	9.9	16.2	319.0	50.1	1.09	21.83
127	9.7	17.6	298.0	52.1	1.09	20.99
128	9.4	16.5	303.0	50.7	1.06	20.89
129	9.1	18.8	316.0	50.3	1.06	21.06
130	8.2	14.5	326.0	52.0	1.07	20.52
Mean	9.33	16.82	310.00	51.69	1.085	20.998
SD	0.51	1.17	11.81	1.20	0.022	0.336
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
181	9.3	16.9	285.0	50.1	1.05	21.05
182	10.2	17.6	354.0	54.1	1.13	20.94
183	9.5	16.7	354.0	52.0	1.08	20.81
184	9.3	16.5	302.0	53.1	1.12	21.10
185	9.0	16.7	318.0	53.0	1.11	21.02
186	9.5	17.7	339.0	50.4	1.07	21.31
187	9.7	17.9	324.0	49.6	1.05	21.20
188	9.6	17.2	311.0	51.2	1.06	20.73
189	8.5	20.7	362.0	51.9	1.08	20.78
190	9.2	17.0	290.0	51.8	1.07	20.69
Mean	9.38	17.49	323.90	51.72	1.082	20.963
SD	0.45	1.22	27.56	1.43	0.029	0.209
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
161	10.3	14.3	109.0	50.5	1.04	20.69
162	10.0	13.8	104.0	51.4	1.07	20.83
163	9.9	13.8	100.0	49.9	1.04	20.85
164	9.5	16.3	231.0	49.9	1.00	20.12
165	9.1	14.7	160.0	50.4	1.04	20.65
Mean	9.76	14.58	140.80	50.42	1.038	20.628
SD	0.47	1.03	55.98	0.61	0.025	0.297
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
11	9.8	14.9	98.7	49.3	1.01	20.42
12	9.6	14.7	105.0	54.3	1.10	20.27
13	9.2	16.0	281.0	52.6	1.05	19.98
14	9.0	16.4	143.0	51.5	1.04	20.29
15	9.5	16.7	194.0	52.3	1.07	20.44
Mean	9.42	15.74	164.34	52.00	1.054	20.280
SD	0.32	0.90	75.46	1.82	0.034	0.184
N	5	5	5	5	5	5

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
41	9.8	16.1	89.4	52.5	1.08	20.49
42	10.4	16.4	87.3	50.7	1.01	20.00
43	10.2	16.3	94.9	51.4	1.05	20.36
44	9.4	14.8	104.0	50.7	1.04	20.48
45	9.9	15.3	102.0	53.1	1.08	20.26
Mean	9.94	15.78	95.52	51.68	1.052	20.318
SD	0.38	0.70	7.40	1.08	0.029	0.201
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
71	9.8	15.1	99.0	51.9	1.07	20.61
72	9.8	15.0	92.3	49.2	1.02	20.68
73	9.9	15.5	93.8	51.4	1.05	20.39
74	9.4	14.8	98.9	51.2	1.03	20.17
75	9.6	17.8	255.0	51.3	1.03	20.04
Mean	9.70	15.64	127.80	51.00	1.040	20.378
SD	0.20	1.23	71.17	1.04	0.020	0.275
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
101	9.9	15.2	119.0	49.6	1.02	20.53
102	10.1	14.9	101.0	50.7	1.02	20.08
103	9.9	15.4	91.0	51.1	1.04	20.32
104	9.9	15.5	107.0	50.0	0.99	19.77
105	9.6	15.1	96.5	53.8	1.07	19.83
Mean	9.88	15.22	102.90	51.04	1.028	20.106
SD	0.18	0.24	10.75	1.65	0.029	0.322
N	5	5	5	5	5	5

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
131	9.3	20.2	261.0	51.0	1.03	20.23
132	9.3	14.8	117.0	50.5	1.02	20.30
133	10.0	15.6	88.7	48.9	1.01	20.58
134	9.4	16.8	100.0	50.6	1.02	20.14
135	10.0	14.9	97.4	50.1	1.02	20.41
Mean	9.60	16.46	132.82	50.22	1.020	20.332
SD	0.37	2.24	72.39	0.80	0.007	0.170
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
191	9.0	15.1	102.0	50.3	1.01	20.18
192	9.9	14.6	91.0	49.1	1.00	20.28
193	10.0	14.7	101.0	49.8	1.03	20.73
194	10.0	18.0	93.8	51.0	1.06	20.72
195	9.1	17.1	131.0	50.6	1.02	20.13
Mean	9.60	15.90	103.76	50.16	1.024	20.408
SD	0.50	1.55	15.93	0.74	0.023	0.294
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
1	7.1	0.69	63.8	12.1	21.0
2	9.7	0.85	81.5	12.3	19.6
3	7.1	0.78	64.2	12.4	20.7
4	8.0	0.72	63.5	13.6	18.5
5	7.4	0.76	70.9	12.8	21.6
11	7.7	0.69	80.0	12.2	21.0
12	8.6	0.97	60.7	12.9	19.0
13	8.2	0.87	76.0	12.4	22.3
14	7.4	0.92	90.6	11.8	22.4
15	7.9	0.65	63.1	12.3	20.8
Mean	7.91	0.790	71.43	12.48	20.69
SD	0.79	0.108	10.12	0.51	1.31
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
31	7.9	1.00	86.8	12.7	22.0
32	7.6	0.90	82.0	13.4	21.8
33	7.5	0.73	97.4	12.8	24.0
34	9.0	0.88	89.8	12.9	22.6
35	8.5	0.94	86.2	13.4	22.0
41	7.6	0.83	90.0	13.5	24.1
42	8.3	0.78	93.5	13.3	23.5
43	9.2	0.82	91.6	13.5	21.1
44	8.9	0.82	90.7	13.6	22.1
45	8.0	0.70	85.7	13.4	24.6
Mean	8.25	0.840	89.37	13.25	22.78
SD	0.63	0.092	4.39	0.32	1.18
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
61	6.9	0.74	78.9	12.0	24.4
62	6.4	0.93	79.6	12.9	23.7
63	8.3	0.81	93.2	12.0	23.2
64	8.2	0.74	80.1	11.2	21.8
65	7.0	0.74	87.1	12.6	24.1
71	8.0	0.98	91.4	11.9	23.8
72	8.0	0.89	91.7	12.4	23.7
73	7.8	0.88	81.4	12.1	22.2
74	7.5	0.77	76.5	11.7	23.3
75	6.2	0.76	79.0	11.8	24.7
Mean	7.43	0.824	83.89	12.06	23.49
SD	0.76	0.089	6.30	0.48	0.91
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
91	8.0	0.72	78.8	12.9	21.8
92	9.1	0.87	67.0	12.2	19.5
93	7.5	0.78	83.7	12.4	21.9
94	8.0	0.96	79.1	12.7	22.2
95	9.1	0.91	76.8	13.0	19.9
101	8.3	0.68	81.8	12.7	23.1
102	7.7	0.94	62.6	13.2	20.4
103	7.4	0.73	74.3	14.0	21.7
104	8.6	0.76	80.8	12.8	20.2
105	7.8	0.79	69.0	12.9	21.4
Mean	8.15	0.814	75.39	12.88	21.21
SD	0.61	0.099	7.01	0.49	1.15
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
121	8.5	0.76	91.9	12.5	25.2
122	7.3	0.82	75.6	12.0	23.4
123	8.1	0.99	72.8	12.3	21.7
124	7.4	0.62	89.9	12.4	25.5
125	7.1	0.87	75.9	11.5	22.6
131	7.2	0.85	79.7	11.8	24.8
132	7.5	0.64	70.0	12.5	23.6
133	8.4	0.89	81.3	11.7	21.6
134	8.2	0.84	92.6	12.4	23.2
135	8.1	0.90	84.6	12.3	22.2
Mean	7.78	0.818	81.43	12.14	23.38
SD	0.53	0.115	8.09	0.36	1.41
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
151	7.8	0.83	91.6	12.6	23.7
152	7.2	0.69	74.9	11.8	23.5
153	8.0	0.81	88.7	12.3	23.5
154	9.1	0.88	85.1	12.3	23.8
155	9.1	1.10	94.1	12.7	24.0
161	7.7	1.00	77.8	12.4	23.0
162	7.2	0.90	81.9	12.1	24.2
163	8.5	0.78	98.2	11.9	23.1
164	7.8	1.00	99.2	12.3	23.2
165	7.4	0.77	89.3	11.7	23.8
Mean	7.98	0.876	88.08	12.21	23.58
SD	0.71	0.126	8.19	0.33	0.39
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
181	8.2	0.69	97.4	12.8	24.1
182	8.1	0.84	76.9	11.8	21.2
183	9.4	0.88	88.3	12.1	25.5
184	8.2	0.69	97.0	12.0	26.0
185	8.1	0.81	95.8	11.8	25.1
191	8.5	0.75	100.5	11.9	24.7
192	9.0	0.63	88.8	12.2	24.4
193	8.6	0.82	76.9	12.2	22.5
194	7.9	1.04	83.7	11.8	22.9
195	8.8	0.88	85.4	11.7	23.2
Mean	8.48	0.803	89.07	12.03	23.96
SD	0.47	0.119	8.48	0.32	1.49
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
151	10.1	0.65	90.3	13.6	21.2
152	10.0 I	0.75 I	99.9 I	12.7 I	23.2 I
153	9.8	0.73	95.5	13.5	21.5
154	10.5	0.72	93.7	13.3	23.1
155	10.2	0.90	93.2	13.2	21.6
156	8.3	0.61	99.3	14.0	24.7
157	10.7	0.62	89.5	13.3	21.1
158	9.3	0.50	88.9	13.0	21.6
159	9.1	0.67	108.8	13.8	24.7
160	7.5	0.58	90.6	12.8	23.4
Mean	9.55	0.673	94.97	13.32	22.61
SD	1.01	0.110	6.21	0.42	1.39
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
1	10.1	1.19	52.1	14.4	18.2
2	12.7	1.01	58.7	15.7	17.2
3	11.2	1.56	54.9	15.6	17.0
4	11.8	1.13	60.6	15.0	16.4
5	10.7	1.35	58.1	16.4	19.1
6	11.3	1.01	55.5	16.1	18.1
7	9.7	1.03	58.5	14.4	19.3
8	10.9	0.96	58.1	15.0	19.3
9	10.3	1.26	53.3	14.7	18.0
10	10.4	1.30	56.1	14.4	18.3
Mean	10.91	1.180	56.59	15.17	18.09
SD	0.88	0.190	2.67	0.74	0.99
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
31	10.9	1.04	62.7	16.0	18.7
32	12.0	1.04	73.6	16.5	19.2
33	10.1	0.72	67.9	16.5	20.9
34	12.8	0.99	73.3	16.4	20.3
35	11.1	1.14	67.9	16.8	19.7
36	12.4	1.06	65.5	17.3	19.0
37	12.2	0.98	72.7	15.6	19.6
38	12.2	0.78	82.6	15.8	21.0
39	12.9	0.68	78.1	15.6	20.2
40	11.3	0.98	64.5	16.2	18.7
Mean	11.79	0.941	70.88	16.27	19.73
SD	0.90	0.157	6.33	0.54	0.85
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
61	9.4	0.66	81.8	13.6	19.9
62	7.5	0.92	84.8	13.8	21.8
63	10.1	0.68	86.3	13.3	19.9
64	8.9	0.68	86.1	13.0	21.3
65	8.1	0.70	77.4	14.4	21.4
66	9.2	0.58	87.7	12.0	20.1
67	8.6	0.59	92.8	13.2	23.1
68	8.0	0.66	94.4	13.3	22.9
69	7.9	0.67	82.4	13.5	21.3
70	9.1	0.76	75.0	13.1	20.4
Mean	8.68	0.690	84.87	13.32	21.21
SD	0.81	0.096	6.09	0.62	1.16
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
91	11.4	1.00	63.2	17.1	19.4
92	12.3	1.08	57.3	16.9	18.4
93	11.8	1.04	61.0	17.2	17.7
94	11.4	1.50	56.6	17.2	18.5
95	12.6	1.12	60.9	17.1	17.9
96	10.0	0.91	65.7	15.2	20.2
97	11.7	1.25	62.2	15.8	17.9
98	11.9	0.95	60.7	17.0	18.1
99	12.1	0.85	61.4	15.6	19.4
100	10.3	1.02	65.0	16.1	18.9
Mean	11.55	1.072	61.40	16.52	18.64
SD	0.83	0.188	2.91	0.76	0.82
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
121	10.0	0.63	88.2	13.4	22.5
122	9.2	0.61	89.6	13.9	21.8
123	8.6	0.88	76.7	14.7	21.1
124	8.4	0.80	78.1	13.7	21.4
125	8.5	0.75	81.7	12.7	20.2
126	10.2	0.75	89.3	13.0	22.4
127	8.3	0.82	86.3	12.6	23.0
128	9.7	0.69	77.3	13.4	20.5
129	8.8	0.61	76.2	12.6	21.2
130	8.7	0.79	88.8	13.2	22.0
Mean	9.04	0.733	83.22	13.32	21.61
SD	0.69	0.094	5.76	0.66	0.90
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
181	8.9	0.67	80.8	13.5	21.0
182	8.5	0.68	78.6	13.3	20.9
183	10.4	0.68	85.7	13.6	23.2
184	9.9	0.73	86.3	12.8	22.7
185	9.9	0.73	84.9	12.7	21.8
186	8.9	0.52	81.4	13.5	21.7
187	8.6	0.73	85.1	12.4	21.1
188	10.0	1.02	81.3	14.4	20.3
189	9.5	0.69	76.5	13.4	20.1
190	9.0	0.78	84.6	13.9	22.0
Mean	9.36	0.723	82.52	13.35	21.48
SD	0.66	0.125	3.31	0.59	0.99
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
161	8.4	0.86	68.4	13.8	20.2
162	8.3	0.92	67.0	12.7	19.5
163	7.2	0.62	81.8	12.8	22.1
164	7.8	0.66	67.5	13.0	19.4
165	8.0	0.83	66.1	12.9	19.9
Mean	7.94	0.778	70.16	13.04	20.22
SD	0.48	0.131	6.56	0.44	1.10
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
11	8.2	0.95	65.2	11.1	19.0
12	9.6	0.90	69.9	11.8	18.2
13	9.6	0.94	67.0	12.5	18.7
14	7.7	0.85	72.5	11.4	20.3
15	9.2	0.69	67.3	10.7	18.3
Mean	8.86	0.866	68.38	11.50	18.90
SD	0.86	0.106	2.85	0.69	0.85
N	5	5	5	5	5

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
41	8.5	0.94	62.6	13.7	17.9
42	8.2	0.96	71.8	13.8	19.3
43	7.7	0.90	63.8	13.2	19.5
44	7.7	0.78	70.1	13.1	21.0
45	8.6	0.93	70.2	13.9	20.1
Mean	8.14	0.902	67.70	13.54	19.56
SD	0.43	0.072	4.18	0.36	1.14
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
71	7.8	0.96	68.6	13.6	20.6
72	8.2	0.72	84.7	13.3	21.6
73	8.7	0.71	74.8	13.4	18.8
74	8.0	0.91	62.2	13.9	20.1
75	7.3	0.85	61.8	14.1	20.6
Mean	8.00	0.830	70.42	13.66	20.34
SD	0.51	0.112	9.60	0.34	1.02
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
101	9.6	0.88	66.0	13.2	19.2
102	8.2	0.71	74.1	13.4	19.9
103	7.2	0.78	68.6	13.3	21.4
104	8.9	0.70	77.9	12.9	18.7
105	8.3	0.86	58.8	14.4	18.9
Mean	8.44	0.786	69.08	13.44	19.62
SD	0.89	0.083	7.39	0.57	1.09
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
131	8.3	0.83	60.5	12.7	18.4
132	9.5	0.78	79.4	13.6	18.8
133	7.0	0.69	76.3	13.4	22.2
134	8.2	0.76	69.5	13.8	18.9
135	9.3	0.81	80.9	13.2	19.2
Mean	8.46	0.774	73.32	13.34	19.50
SD	1.00	0.054	8.40	0.42	1.54
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
191	8.0	0.74	70.9	12.8	19.5
192	8.3	0.92	77.1	13.6	21.1
193	7.8	0.85	62.6	14.0	20.9
194	8.4	1.03	74.8	12.8	18.5
195	8.3	0.67	60.9	13.1	19.0
Mean	8.16	0.842	69.26	13.26	19.80
SD	0.25	0.143	7.23	0.53	1.15
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
16	8.0	7.01	4.85	3.3	230.3	867	37.2
17	9.0	7.70	6.03	2.5	193.1	970	42.6
18	9.2	7.67	8.81	1.8	139.2	876	43.9
19	9.1	7.83	14.85	2.2	171.5	972	43.3
20	8.8	7.37	8.34	2.5	182.1	820	40.9
26	9.2	7.74	13.53	2.4	187.4	874	43.2
27	9.2	7.80	7.30	3.3	257.5	1063	44.0
28	8.1	7.28	7.29	2.5	182.9	858	38.1
29	9.3	7.97	6.77	2.3	185.1	1248	43.9
30	8.8	8.17	6.40	2.8	227.8	1203	41.6
Mean	8.87	7.654	8.417	2.56	195.69	975.1	41.87
SD	0.46	0.344	3.256	0.47	33.93	150.4	2.45
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
46	8.4	7.09	11.13	1.7	117.1	628	39.9
47	9.4	8.02	11.27	0.6	45.4	830	44.0
48	8.5	7.12	15.33	1.2	83.2	1021	40.5
49	8.6	7.59	13.35	1.0	72.1	566	41.0
50	8.4	7.13	11.88	1.1	78.8	606	39.0
56	8.7	7.32	14.90	0.5	39.5	743	41.3
57	8.6	7.39	11.66	0.6	45.8	828	40.0
58	8.1	6.83	12.25	1.2	82.4	726	38.0
59	8.8	7.40	12.00	0.8	60.0	789	41.5
60	8.2	7.06	15.16	1.0	73.2	799	38.9
Mean	8.57	7.295	12.893	0.97	69.75	753.6	40.41
SD	0.36	0.334	1.660	0.36	23.24	133.3	1.69
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
76	9.7	8.47	9.12	1.4	118.0	1436	44.8
77	8.9	7.77	8.21	1.1	83.9	1061	41.6
78	9.2	7.55	12.17	1.3	95.1	1292	42.4
79	8.3	6.99	3.92	2.0	141.2	715	37.6
80	9.3	8.09	6.64	0.8	61.7	1070	43.3
86	9.3	8.19	7.21	0.8	67.4	868	42.5
87	9.0	7.66	11.75	1.4	104.2	1427	43.0
88	9.2	7.95	10.58	1.1	90.4	956	42.8
89	9.3	7.84	8.74	1.3	101.1	916	43.1
90	9.0	7.56	8.85	1.1	85.8	942	41.2
Mean	9.12	7.807	8.719	1.23	94.88	1068.3	42.23
SD	0.36	0.409	2.464	0.35	23.30	242.8	1.90
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
106	8.2	6.76	8.15	1.8	121.9	1091	39.2
107	8.9	7.87	6.56	2.0	156.0	919	42.7
108	8.6	7.52	8.43	1.1	84.9	945	40.8
109	8.6	6.99	8.57	2.1	146.8	1264	40.6
110	8.8	7.46	8.05	0.9	67.1	1051	42.2
116	8.8	7.47	7.41	1.9	143.2	1004	42.0
117	9.0	8.14	9.15	2.4	191.7	820	43.5
118	8.4	7.41	12.45	2.8	204.7	862	39.9
119	8.4	7.19	5.42	1.9	133.0	903	38.9
120	9.3	8.25	8.92	2.3	189.2	998	44.1
Mean	8.70	7.506	8.311	1.92	143.85	985.7	41.39
SD	0.33	0.474	1.844	0.57	44.93	128.7	1.79
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
136	8.2	7.71	7.28	1.6	124.4	873	39.7
137	8.5	7.40	10.51	1.1	81.7	1097	40.1
138	8.1	7.14	5.71	1.6	116.1	970	37.3
139	8.9	7.94	9.56	1.7	137.0	1153	42.0
140	8.9	7.66	11.59	1.2	93.8	972	41.3
146	8.6	7.69	8.20	1.5	118.9	856	40.9
147	9.1	7.85	9.79	1.1	89.8	1202	42.9
148	8.8	7.21	8.87	1.7	120.1	1063	41.1
149	8.5	7.57	7.90	1.9	144.6	1201	39.6
150	8.6	7.72	11.08	1.3	96.9	1099	40.0
Mean	8.62	7.589	9.049	1.47	112.33	1048.6	40.49
SD	0.32	0.262	1.822	0.28	20.92	125.9	1.54
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
166	8.3	7.02	8.18	1.2	86.9	908	37.6
167	9.0	7.35	15.37	1.3	93.9	811	41.2
168	8.9	7.99	7.10	0.9	69.6	1163	41.0
169	8.5	7.51	8.12	1.0	77.8	1230	39.4
170	9.3	8.01	12.32	0.7	56.4	914	41.7
176	9.1	7.79	11.53	1.0	76.4	978	42.0
177	8.2	7.39	6.95	1.0	76.8	1038	38.1
178	8.6	7.43	11.38	1.0	72.7	808	40.2
179	8.9	7.32	11.92	1.1	83.9	1141	41.0
180	9.0	7.95	7.42	1.3	101.9	1011	40.9
Mean	8.78	7.576	10.029	1.05	79.63	1000.2	40.31
SD	0.36	0.339	2.855	0.18	12.83	145.2	1.49
N	10	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
196	8.3	7.17	11.38	1.5	106.8	959	38.3
197	8.6	7.35	10.95	1.2	90.0	990	39.8
198	9.0	8.09	9.43	1.7	133.7	923	41.9
199	8.9	7.54	9.26	0.8	63.3	1020	41.8
200	8.2	7.23	6.17	1.0	69.4	965	37.5
206	9.3	7.15	10.28	1.2	87.5	878	37.8
207	9.1	8.05	9.67	1.3	101.6	1025	42.7
208	8.8	8.31	17.63	1.9	154.7	970	41.0
209	8.7	7.73	9.04	1.6	122.5	1261	40.6
210	8.5	7.16	10.14	1.2	83.6	1174	40.1
Mean	8.74	7.578	10.395	1.34	101.31	1016.5	40.15
SD	0.35	0.440	2.908	0.33	28.82	116.2	1.80
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
166	7.9	6.67	11.87	3.2	213.1	561	36.0
167	8.3	6.97	18.90	2.8	192.9	542	38.4
168	8.5	7.82	13.17	2.2	168.5	656	39.5
169	8.0	7.07	11.62	3.7	258.2	774	37.2
170	8.5	7.52	17.21	2.3	176.5	574	39.0
171	8.8	7.75	15.70	1.4	109.9	499	40.5
172	8.6	7.36	14.23	2.9	212.6	291	39.5
173	9.0	8.47	17.48	1.5	127.0	462	41.3
174	8.3	7.34	17.15	2.3	170.0	561	37.9
175	8.4	7.22	15.34	3.0	215.7	784	39.3
Mean	8.43	7.419	15.267	2.53	184.44	570.4	38.86
SD	0.33	0.508	2.493	0.73	44.08	145.4	1.55
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
16	8.6	7.60	4.34	2.7	201.5	968	41.1
17	9.6	8.16	4.50	1.7	138.8	1259	45.5
18	9.3	8.01	5.88	2.9	228.3	923	45.5
19	9.0	7.86	11.29	2.7	213.6	1098	42.8
20	9.3	8.04	10.39	2.2	176.0	883	44.0
21	8.7	7.51	6.73	2.9	219.1	927	42.1
22	8.6	7.84	5.54	2.1	164.0	1168	40.6
23	9.2	8.03	8.06	2.2	179.4	1032	44.6
24	9.5	8.08	8.70	2.6	210.8	1177	45.4
25	9.0	7.79	5.63	3.6	278.0	1246	42.9
Mean	9.08	7.892	7.106	2.56	200.95	1068.1	43.45
SD	0.36	0.213	2.414	0.53	38.85	140.4	1.83
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
46	8.3	7.16	12.57	2.5	180.3	460	39.5
47	9.4	8.20	10.21	1.7	136.8	520	45.7
48	8.8	7.51	23.55	2.2	165.8	912	42.8
49	8.5	7.38	8.62	3.6	266.9	397	41.1
50	8.6	7.52	13.64	3.4	258.3	524	41.9
51	8.5	7.55	16.49	2.8	214.1	674	40.7
52	8.7	7.64	17.05	3.6	273.9	623	42.4
53	8.7	7.55	15.06	2.5	191.0	795	41.8
54	8.9	7.93	14.77	1.9	154.3	668	42.7
55	8.2	7.02	13.04	2.2	156.3	656	38.8
Mean	8.66	7.546	14.500	2.64	199.77	622.9	41.74
SD	0.34	0.340	4.114	0.69	50.73	155.2	1.92
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
76	8.7	7.90	13.75	3.7	290.4	932	41.8
77	8.2	7.31	10.64	3.1	223.4	855	39.5
78	8.7	7.34	11.29	3.2	231.9	892	40.6
79	8.1	6.94	8.40	4.8	329.7	482	38.1
80	8.3	7.50	11.18	2.0	147.6	633	38.9
81	8.6	7.52	7.18	2.1	156.6	580	40.1
82	8.5	7.66	8.50	3.8	290.7	846	39.2
83	8.6	7.87	14.44	3.3	259.2	588	39.4
84	8.4	7.44	10.86	2.3	172.6	521	38.9
85	7.7	7.17	13.92	2.1	153.3	652	35.9
Mean	8.38	7.465	11.016	3.04	225.54	698.1	39.24
SD	0.32	0.298	2.490	0.92	66.10	166.4	1.56
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
106	7.8	6.63	13.41	3.3	220.8	1022	38.1
107	8.2	7.43	9.89	2.7	198.4	803	39.5
108	8.2	7.43	15.17	2.3	174.4	924	40.1
109	8.6	7.20	13.13	4.1	297.7	939	41.9
110	8.0	6.93	14.87	3.6	248.3	986	38.7
111	8.3	7.59	16.75	2.4	185.2	880	40.0
112	7.6	7.18	6.20	2.9	211.3	825	37.2
113	7.9	7.20	8.53	2.8	203.1	603	39.0
114	8.0	7.31	17.51	2.5	184.9	875	39.0
115	8.7	7.58	11.98	2.3	174.8	911	41.5
Mean	8.13	7.248	12.744	2.89	209.89	876.8	39.50
SD	0.34	0.296	3.637	0.60	38.31	117.1	1.44
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
136	7.2	6.86	13.94	3.8	260.7	805	34.2
137	8.3	7.60	20.24	2.7	205.1	723	39.7
138	7.2	6.61	12.05	4.1	273.1	750	34.5
139	7.8	7.20	16.30	3.3	239.8	555	37.6
140	8.0	7.16	14.54	2.6	186.8	586	38.2
141	8.0	7.51	11.51	2.9	215.6	815	37.2
142	8.8	7.68	11.99	2.6	202.0	600	41.4
143	7.8	6.97	15.11	4.4	308.7	553	36.4
144	8.0	7.02	15.70	2.4	169.7	849	37.2
145	7.4	6.84	12.67	3.0	205.1	786	34.2
Mean	7.85	7.145	14.405	3.18	226.66	702.2	37.06
SD	0.50	0.355	2.642	0.70	43.09	116.6	2.38
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
196	7.3	6.55	16.58	3.8	250.1	792	34.7
197	7.8	6.89	13.40	2.3	160.0	765	37.2
198	8.2	7.59	18.97	2.3	176.1	812	39.7
199	8.3	7.28	15.22	1.9	137.8	658	39.2
200	7.6	6.97	14.01	3.2	220.8	663	35.3
201	8.4	7.23	16.37	3.0	219.3	752	39.4
202	8.2	7.36	12.99	2.8	207.6	596	39.5
203	8.0	7.21	15.39	2.3	166.0	759	37.6
204	7.7	6.97	19.03	2.9	204.6	889	36.9
205	7.8	7.10	8.01	3.3	237.2	358	36.4
Mean	7.93	7.115	14.997	2.78	197.95	704.4	37.59
SD	0.35	0.288	3.215	0.58	36.41	148.3	1.81
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
176	8.6	7.87	5.63	3.8	300.6	1209	41.6
177	8.8	8.27	5.16	2.3	189.7	998	41.7
178	8.9	8.22	4.61	3.3	268.0	839	42.6
179	8.8	7.73	8.04	3.3	258.3	988	40.9
180	9.1	8.62	4.13	2.6	224.9	1095	43.8
Mean	8.84	8.142	5.514	3.06	248.30	1025.8	42.12
SD	0.18	0.352	1.521	0.60	42.44	137.3	1.12
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
26	8.8	8.10	8.20	2.6	210.9	992	42.8
27	9.1	8.06	5.64	3.3	265.2	1005	44.0
28	8.3	7.89	6.69	4.4	344.9	514	40.0
29	9.0	8.34	5.29	3.2	268.6	1242	43.6
30	8.8	8.49	4.60	2.5	209.8	996	42.1
Mean	8.80	8.176	6.084	3.20	259.88	949.8	42.50
SD	0.31	0.238	1.403	0.76	55.32	265.6	1.58
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
56	9.2	8.35	7.57	2.1	177.2	1130	45.3
57	8.6	7.87	7.46	2.4	192.2	932	41.4
58	8.1	7.48	7.81	3.5	264.1	1014	40.2
59	8.6	7.55	3.40	4.7	355.9	828	42.2
60	8.8	8.30	11.87	2.3	192.6	798	42.6
Mean	8.66	7.910	7.622	3.00	236.40	940.4	42.34
SD	0.40	0.407	2.997	1.10	74.87	136.3	1.89
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
86	9.2	8.74	7.03	2.8	246.6	999	44.0
87	8.7	7.99	10.04	2.6	209.7	1319	42.2
88	9.1	8.31	7.97	2.3	187.7	882	44.4
89	8.9	8.04	5.57	1.8	145.6	946	43.2
90	9.3	8.48	4.45	1.9	158.1	818	44.4
Mean	9.04	8.312	7.012	2.28	189.54	992.8	43.64
SD	0.24	0.312	2.164	0.43	40.57	194.6	0.94
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
116	9.1	8.35	4.58	3.0	246.8	830	44.0
117	8.9	8.72	8.45	2.6	227.5	840	43.5
118	8.8	8.62	11.45	2.4	207.6	932	43.2
119	8.6	7.73	4.17	2.8	214.6	760	40.9
120	9.6	9.37	7.76	2.1	200.6	763	46.9
Mean	9.00	8.558	7.282	2.58	219.42	825.0	43.70
SD	0.38	0.595	2.998	0.35	18.25	70.3	2.15
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
146	8.8	8.46	7.57	1.0	88.6	721	43.0
147	8.3	7.52	4.92	3.4	255.9	1087	40.8
148	8.7	7.86	5.53	2.4	189.1	800	42.4
149	8.5	8.16	10.05	2.3	187.0	906	40.8
150	9.2	8.61	6.08	2.5	216.2	943	44.6
Mean	8.70	8.122	6.830	2.32	187.36	891.4	42.32
SD	0.34	0.443	2.050	0.86	61.82	140.1	1.60
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
206	9.2	8.79	6.31	1.8	158.9	797	45.0
207	8.8	8.18	8.87	1.8	144.1	942	42.5
208	8.9	9.02	9.69	2.4	217.1	1040	43.7
209	8.8	8.12	3.56	2.3	189.9	1068	42.8
210	9.1	8.12	7.17	3.0	241.4	1145	43.8
Mean	8.96	8.446	7.120	2.26	190.28	998.4	43.56
SD	0.18	0.428	2.398	0.50	40.16	134.0	0.98
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
16	14.3	80.9	2.5	1.6	0.5	0.2
17	27.4	64.5	3.8	3.3	0.9	0.2
18	16.0	79.4	2.4	1.0	0.9	0.3
19	7.6	87.3	2.1	1.0	1.5	0.5
20	6.8	88.8	1.4	1.5	1.1	0.3
26	7.7	87.7	1.8	1.4	1.2	0.3
27	19.4	75.3	2.7	1.3	1.0	0.2
28	15.8	80.2	1.9	1.2	0.8	0.2
29	15.8	76.4	3.3	3.4	0.7	0.4
30	15.5	80.6	1.6	1.1	0.9	0.2
Mean	14.63	80.11	2.35	1.68	0.95	0.28
SD	6.24	7.20	0.76	0.90	0.28	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
46	28.7	61.5	3.3	1.5	4.6	0.4
47	23.9	63.8	3.0	0.9	7.9	0.4
48	28.8	63.0	3.9	0.8	3.0	0.4
49	32.1	57.4	2.9	1.3	5.7	0.5
50	29.3	63.0	3.0	1.7	2.5	0.5
56	34.1	55.2	2.4	1.2	6.7	0.5
57	30.7	62.0	2.5	2.2	2.1	0.5
58	35.1	55.7	2.9	1.0	4.9	0.3
59	24.9	63.5	4.6	1.9	4.6	0.5
60	28.8	60.8	5.0	1.3	3.6	0.5
Mean	29.64	60.59	3.35	1.38	4.56	0.45
SD	3.57	3.27	0.87	0.45	1.85	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
76	13.3	78.7	2.9	1.7	2.9	0.3
77	12.7	80.6	2.9	1.8	1.7	0.3
78	11.2	82.1	2.6	0.9	2.6	0.5
79	12.4	79.3	3.8	1.4	2.9	0.2
80	15.3	77.2	3.3	1.8	2.1	0.4
86	10.6	84.9	1.6	1.1	1.4	0.4
87	7.1	87.9	2.1	0.7	1.7	0.5
88	13.7	80.8	2.8	1.0	1.3	0.4
89	12.1	82.2	2.0	0.8	2.5	0.4
90	21.2	71.6	3.1	1.3	2.5	0.3
Mean	12.96	80.53	2.71	1.25	2.16	0.37
SD	3.62	4.40	0.66	0.41	0.60	0.09
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
106	13.1	81.0	2.4	1.4	1.6	0.4
107	10.0	83.3	1.6	4.0	0.8	0.3
108	18.5	75.9	2.8	1.0	1.5	0.4
109	11.2	81.5	2.4	3.0	1.5	0.4
110	13.4	81.3	2.4	1.3	1.4	0.2
116	11.2	83.9	1.8	1.7	1.1	0.3
117	12.6	82.5	1.7	1.6	1.2	0.4
118	11.9	82.2	2.4	1.7	1.3	0.5
119	14.3	80.2	2.3	1.7	1.2	0.2
120	18.9	75.6	1.9	2.0	1.2	0.4
Mean	13.51	80.74	2.17	1.94	1.28	0.35
SD	3.00	2.85	0.39	0.90	0.23	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
136	12.9	81.6	2.2	0.7	2.1	0.4
137	18.8	75.0	2.0	2.1	1.8	0.3
138	13.8	82.4	1.3	1.0	1.1	0.3
139	15.6	79.2	1.8	1.0	2.0	0.3
140	32.2	60.7	2.1	0.8	3.8	0.3
146	11.2	82.0	2.7	1.3	2.4	0.4
147	15.5	78.2	3.0	0.9	2.0	0.5
148	15.8	77.0	3.1	1.0	2.9	0.2
149	12.6	79.1	1.6	1.7	4.6	0.4
150	32.3	54.6	2.4	1.1	9.1	0.5
Mean	18.07	74.98	2.22	1.16	3.18	0.36
SD	7.76	9.53	0.59	0.43	2.32	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
166	24.3	66.5	4.0	0.9	3.9	0.3
167	19.8	72.2	4.0	1.0	2.5	0.5
168	29.3	61.3	2.7	1.7	4.5	0.5
169	19.6	71.9	4.1	1.3	2.7	0.5
170	24.0	69.1	3.2	1.1	2.1	0.4
176	26.1	64.1	2.7	0.9	5.7	0.6
177	22.4	67.7	3.4	3.1	3.0	0.4
178	23.6	68.4	2.9	1.6	3.1	0.3
179	19.9	70.6	4.4	1.2	3.3	0.6
180	20.4	69.0	5.4	1.7	3.1	0.3
Mean	22.94	68.08	3.68	1.45	3.39	0.44
SD	3.18	3.41	0.86	0.66	1.06	0.12
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
196	19.0	76.1	1.8	0.9	1.7	0.5
197	26.7	62.5	2.7	1.5	6.1	0.4
198	18.7	76.6	1.2	1.4	1.8	0.3
199	12.6	80.9	2.0	1.6	2.6	0.4
200	28.8	61.1	3.9	2.5	3.5	0.2
206	28.8	65.6	2.1	1.0	2.2	0.4
207	26.3	66.0	2.0	1.2	4.2	0.4
208	32.8	59.1	2.1	1.8	3.7	0.4
209	20.3	71.9	1.7	2.8	2.9	0.4
210	22.7	67.2	2.5	1.1	6.0	0.5
Mean	23.67	68.70	2.20	1.58	3.47	0.39
SD	6.09	7.33	0.73	0.63	1.58	0.09
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
166	39.8	52.0	1.8	0.8	5.3	0.3
167	36.2	56.0	2.5	0.8	4.2	0.4
168	45.8	44.6	3.1	0.7	5.3	0.4
169	41.0	48.7	2.4	0.4	7.2	0.3
170	46.0	45.7	2.3	0.6	5.0	0.4
171	47.5	41.0	3.5	0.6	7.0	0.3
172	54.1	36.8	2.1	0.5	6.1	0.4
173	32.2	58.7	1.5	0.2	6.8	0.6
174	39.4	50.7	2.5	0.4	6.7	0.4
175	50.3	41.2	3.6	0.9	3.8	0.2
Mean	43.23	47.54	2.53	0.59	5.74	0.37
SD	6.69	6.97	0.69	0.22	1.20	0.11
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
16	20.6	74.4	3.2	1.0	0.7	0.1
17	28.3	65.1	3.6	2.2	0.6	0.2
18	13.7	82.1	1.6	1.3	0.9	0.3
19	11.5	83.1	2.2	1.8	1.1	0.3
20	7.9	86.6	2.5	1.2	1.4	0.3
21	9.7	85.6	2.3	1.0	1.2	0.2
22	13.0	81.7	3.0	1.1	1.0	0.1
23	11.0	83.4	2.7	1.1	1.6	0.2
24	13.9	80.3	3.3	1.1	1.0	0.3
25	15.9	79.6	2.7	1.0	0.5	0.3
Mean	14.55	80.19	2.71	1.28	1.00	0.23
SD	5.97	6.30	0.59	0.40	0.35	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
46	34.9	57.9	1.5	0.7	4.5	0.4
47	42.2	52.5	1.2	0.8	2.6	0.6
48	53.4	34.6	4.0	0.5	7.0	0.6
49	39.0	52.4	2.1	0.6	5.5	0.4
50	55.2	38.6	1.9	0.9	3.1	0.3
51	34.4	54.8	2.6	0.5	7.2	0.5
52	43.8	42.0	3.2	0.8	9.8	0.4
53	45.7	42.9	2.7	0.5	7.9	0.4
54	43.4	48.3	2.7	1.0	4.2	0.3
55	50.3	41.9	2.1	0.8	4.7	0.3
Mean	44.23	46.59	2.40	0.71	5.65	0.42
SD	7.15	7.68	0.82	0.18	2.28	0.11
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
76	39.6	48.9	5.3	1.5	4.4	0.2
77	36.1	57.1	4.1	0.9	1.5	0.2
78	36.4	53.4	3.4	1.4	5.1	0.4
79	35.1	55.9	4.6	1.1	3.2	0.3
80	43.0	48.4	4.2	0.9	3.1	0.4
81	45.4	45.2	4.6	1.2	3.2	0.4
82	45.0	44.1	3.5	4.5	2.4	0.5
83	37.3	50.8	3.0	0.9	7.6	0.4
84	33.0	51.6	4.6	1.3	9.0	0.5
85	30.0	63.5	3.0	0.9	2.3	0.4
Mean	38.09	51.89	4.03	1.46	4.18	0.37
SD	5.11	5.85	0.78	1.09	2.42	0.11
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
106	32.6	58.5	3.1	1.7	3.8	0.3
107	25.8	65.3	2.8	3.8	2.0	0.3
108	57.5	32.3	3.0	1.8	5.1	0.3
109	35.9	54.3	4.2	2.5	2.7	0.4
110	48.2	42.0	3.2	1.8	4.6	0.3
111	43.0	44.7	5.3	2.8	3.8	0.4
112	46.2	45.0	3.4	2.8	2.4	0.2
113	42.6	47.2	3.9	2.6	3.4	0.3
114	44.8	48.1	2.5	2.0	2.2	0.4
115	52.9	37.8	3.5	3.2	2.4	0.3
Mean	42.95	47.52	3.49	2.50	3.24	0.32
SD	9.45	9.74	0.81	0.69	1.07	0.06
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
136	50.7	39.4	2.7	2.3	4.6	0.3
137	54.0	32.1	3.4	3.6	6.6	0.4
138	38.5	51.9	3.3	4.2	1.9	0.2
139	44.6	46.5	3.2	3.3	2.1	0.3
140	46.4	40.1	2.9	3.4	6.8	0.4
141	58.9	30.3	2.9	4.4	3.3	0.2
142	47.5	45.0	3.1	1.6	2.5	0.4
143	45.8	45.3	1.2	3.8	3.5	0.3
144	52.1	35.2	2.5	4.1	5.9	0.3
145	42.0	45.5	3.0	4.5	4.8	0.2
Mean	48.05	41.13	2.82	3.52	4.20	0.30
SD	6.00	6.95	0.63	0.93	1.82	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
196	45.0	43.5	2.0	3.6	5.6	0.2
197	44.9	46.1	1.3	3.5	4.0	0.3
198	60.0	31.3	2.7	3.4	2.3	0.3
199	49.3	39.5	2.3	4.2	4.4	0.3
200	59.3	29.6	2.2	4.0	4.7	0.2
201	60.0	31.5	0.9	4.1	3.1	0.3
202	44.0	44.6	1.7	6.2	3.1	0.3
203	43.2	47.6	2.6	2.3	4.2	0.2
204	39.1	52.1	2.6	3.9	2.1	0.3
205	42.2	50.7	1.8	2.8	2.4	0.2
Mean	48.70	41.65	2.01	3.80	3.59	0.26
SD	8.05	8.29	0.59	1.03	1.17	0.05
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
176	11.2	83.9	2.1	1.5	1.0	0.3
177	18.5	75.2	2.6	2.9	0.5	0.3
178	10.4	84.1	2.7	1.4	1.3	0.2
179	16.6	76.9	4.0	1.4	0.9	0.3
180	14.9	78.7	2.5	2.8	1.0	0.1
Mean	14.32	79.76	2.78	2.00	0.94	0.24
SD	3.47	4.06	0.72	0.78	0.29	0.09
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
26	11.6	83.8	2.7	0.8	1.0	0.2
27	21.6	71.6	2.2	3.8	0.6	0.2
28	16.4	76.6	3.8	1.5	1.4	0.3
29	18.9	70.6	3.6	6.0	0.8	0.2
30	9.4	82.7	3.3	3.2	1.1	0.3
Mean	15.58	77.06	3.12	3.06	0.98	0.24
SD	5.05	6.10	0.66	2.05	0.30	0.05
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
56	15.7	78.4	2.8	1.6	1.1	0.4
57	14.2	80.3	1.7	2.3	1.3	0.2
58	12.9	81.4	2.9	1.1	1.6	0.2
59	20.2	75.3	2.0	1.5	0.8	0.2
60	16.4	77.9	3.2	1.4	0.8	0.3
Mean	15.88	78.66	2.52	1.58	1.12	0.26
SD	2.77	2.35	0.64	0.44	0.34	0.09
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
86	12.4	83.0	2.4	0.9	1.2	0.1
87	11.2	82.9	3.4	1.0	1.2	0.3
88	17.0	75.3	4.0	2.2	1.2	0.3
89	15.4	80.1	2.4	1.1	0.8	0.3
90	18.8	72.0	3.4	5.1	0.6	0.1
Mean	14.96	78.66	3.12	2.06	1.00	0.22
SD	3.15	4.86	0.70	1.78	0.28	0.11
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
116	26.8	64.9	2.3	5.1	0.7	0.2
117	17.6	76.0	3.3	1.3	1.5	0.2
118	13.6	80.0	2.7	2.1	1.3	0.3
119	18.6	74.4	3.7	1.9	1.3	0.1
120	16.5	77.7	3.2	1.7	0.7	0.3
Mean	18.62	74.60	3.04	2.42	1.10	0.22
SD	4.94	5.81	0.55	1.53	0.37	0.08
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
146	14.6	79.0	3.6	1.7	0.8	0.3
147	21.3	72.9	3.7	1.2	0.8	0.1
148	24.0	70.5	2.8	1.6	1.0	0.1
149	10.7	84.2	2.3	1.6	1.0	0.2
150	20.4	73.0	3.7	1.4	1.2	0.2
Mean	18.20	75.92	3.22	1.50	0.96	0.18
SD	5.42	5.59	0.64	0.20	0.17	0.08
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
206	19.2	74.0	2.3	3.2	1.1	0.2
207	16.3	78.3	2.4	1.6	1.1	0.3
208	12.1	82.7	2.6	1.5	0.9	0.2
209	18.9	75.6	2.8	1.8	0.7	0.2
210	22.5	72.4	1.9	2.1	0.8	0.4
Mean	17.80	76.60	2.40	2.04	0.92	0.26
SD	3.87	4.05	0.34	0.69	0.18	0.09
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
16	0.69	3.93	0.12	0.08	0.03	0.01
17	1.65	3.89	0.23	0.20	0.05	0.01
18	1.41	7.00	0.21	0.09	0.08	0.03
19	1.13	12.96	0.31	0.15	0.22	0.07
20	0.57	7.41	0.12	0.13	0.09	0.03
26	1.04	11.86	0.24	0.20	0.16	0.04
27	1.42	5.50	0.20	0.10	0.07	0.02
28	1.15	5.84	0.14	0.09	0.06	0.01
29	1.07	5.17	0.23	0.23	0.05	0.02
30	0.99	5.16	0.10	0.07	0.06	0.02
Mean	1.112	6.872	0.190	0.134	0.087	0.026
SD	0.328	3.137	0.067	0.058	0.059	0.018
N	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
46	3.19	6.85	0.37	0.16	0.52	0.04
47	2.69	7.19	0.34	0.10	0.89	0.05
48	4.42	9.66	0.60	0.13	0.45	0.07
49	4.28	7.67	0.39	0.18	0.76	0.07
50	3.48	7.49	0.35	0.20	0.30	0.06
56	5.08	8.22	0.35	0.17	1.00	0.07
57	3.58	7.23	0.29	0.26	0.25	0.05
58	4.30	6.83	0.36	0.12	0.60	0.04
59	2.99	7.62	0.55	0.23	0.55	0.05
60	4.36	9.22	0.76	0.20	0.55	0.07
Mean	3.837	7.798	0.436	0.175	0.587	0.057
SD	0.761	0.963	0.150	0.050	0.239	0.013
N	10	10	10	10	10	10

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
76	1.21	7.18	0.27	0.16	0.27	0.03
77	1.04	6.62	0.23	0.15	0.14	0.03
78	1.36	9.99	0.32	0.11	0.32	0.07
79	0.49	3.11	0.15	0.05	0.11	0.01
80	1.01	5.13	0.22	0.12	0.14	0.02
86	0.77	6.12	0.12	0.08	0.10	0.03
87	0.84	10.33	0.24	0.08	0.20	0.06
88	1.45	8.55	0.29	0.10	0.14	0.05
89	1.05	7.18	0.17	0.07	0.22	0.03
90	1.87	6.34	0.27	0.12	0.22	0.03
Mean	1.109	7.055	0.228	0.104	0.186	0.036
SD	0.388	2.172	0.064	0.035	0.072	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
106	1.07	6.60	0.20	0.11	0.13	0.03
107	0.66	5.47	0.10	0.26	0.05	0.02
108	1.56	6.40	0.24	0.09	0.12	0.03
109	0.96	6.98	0.21	0.26	0.13	0.03
110	1.08	6.54	0.19	0.11	0.12	0.02
116	0.83	6.22	0.13	0.13	0.08	0.02
117	1.15	7.55	0.16	0.15	0.11	0.04
118	1.48	10.23	0.30	0.21	0.16	0.06
119	0.78	4.35	0.13	0.09	0.07	0.01
120	1.68	6.75	0.17	0.17	0.11	0.04
Mean	1.125	6.709	0.183	0.158	0.108	0.030
SD	0.346	1.515	0.059	0.065	0.033	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
136	0.94	5.94	0.16	0.05	0.15	0.03
137	1.98	7.88	0.21	0.22	0.19	0.03
138	0.79	4.70	0.08	0.06	0.06	0.02
139	1.49	7.57	0.17	0.10	0.20	0.03
140	3.73	7.03	0.25	0.10	0.44	0.04
146	0.92	6.73	0.22	0.11	0.19	0.03
147	1.51	7.65	0.29	0.09	0.19	0.04
148	1.41	6.83	0.27	0.09	0.26	0.02
149	0.99	6.25	0.12	0.13	0.36	0.03
150	3.58	6.05	0.27	0.12	1.01	0.06
Mean	1.734	6.663	0.204	0.107	0.305	0.033
SD	1.075	0.964	0.070	0.047	0.270	0.012
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
166	1.98	5.44	0.33	0.08	0.32	0.03
167	3.04	11.10	0.62	0.15	0.39	0.07
168	2.08	4.35	0.19	0.12	0.32	0.04
169	1.59	5.84	0.33	0.11	0.22	0.04
170	2.96	8.51	0.40	0.14	0.26	0.05
176	3.00	7.39	0.31	0.10	0.65	0.07
177	1.55	4.70	0.24	0.22	0.21	0.03
178	2.69	7.79	0.33	0.18	0.35	0.04
179	2.37	8.41	0.53	0.14	0.39	0.07
180	1.52	5.12	0.40	0.13	0.23	0.03
Mean	2.278	6.865	0.368	0.137	0.334	0.047
SD	0.619	2.142	0.128	0.040	0.130	0.017
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
196	2.16	8.66	0.20	0.10	0.20	0.06
197	2.93	6.84	0.30	0.17	0.67	0.05
198	1.77	7.22	0.11	0.13	0.17	0.03
199	1.16	7.49	0.18	0.15	0.24	0.04
200	1.78	3.77	0.24	0.16	0.21	0.01
206	2.96	6.74	0.22	0.10	0.22	0.04
207	2.54	6.38	0.19	0.12	0.41	0.04
208	5.79	10.41	0.38	0.33	0.66	0.07
209	1.84	6.50	0.15	0.25	0.26	0.04
210	2.30	6.81	0.26	0.11	0.61	0.05
Mean	2.523	7.082	0.223	0.162	0.365	0.043
SD	1.276	1.693	0.077	0.074	0.205	0.016
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
166	4.72	6.17	0.21	0.10	0.63	0.03
167	6.83	10.58	0.47	0.15	0.80	0.07
168	6.03	5.87	0.41	0.10	0.69	0.06
169	4.76	5.65	0.28	0.05	0.83	0.04
170	7.92	7.86	0.40	0.11	0.86	0.06
171	7.46	6.44	0.55	0.10	1.10	0.05
172	7.70	5.24	0.30	0.08	0.87	0.05
173	5.63	10.26	0.27	0.03	1.19	0.10
174	6.76	8.69	0.42	0.06	1.15	0.06
175	7.71	6.32	0.55	0.14	0.58	0.03
Mean	6.552	7.308	0.386	0.092	0.870	0.055
SD	1.209	1.937	0.118	0.038	0.215	0.021
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
16	0.89	3.23	0.14	0.04	0.03	0.01
17	1.27	2.93	0.16	0.10	0.03	0.01
18	0.81	4.83	0.09	0.08	0.05	0.02
19	1.29	9.38	0.25	0.21	0.12	0.03
20	0.83	9.00	0.26	0.13	0.15	0.03
21	0.66	5.76	0.16	0.07	0.08	0.01
22	0.72	4.53	0.17	0.06	0.06	0.01
23	0.88	6.72	0.22	0.09	0.13	0.02
24	1.21	6.98	0.29	0.10	0.09	0.03
25	0.89	4.48	0.15	0.06	0.03	0.02
Mean	0.945	5.784	0.189	0.094	0.077	0.019
SD	0.228	2.222	0.063	0.048	0.044	0.009
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
46	4.39	7.28	0.19	0.08	0.57	0.05
47	4.31	5.37	0.12	0.08	0.27	0.06
48	12.57	8.15	0.94	0.12	1.64	0.13
49	3.36	4.52	0.18	0.05	0.48	0.03
50	7.53	5.27	0.26	0.12	0.42	0.04
51	5.67	9.04	0.43	0.08	1.19	0.08
52	7.46	7.17	0.55	0.14	1.66	0.06
53	6.88	6.46	0.40	0.07	1.18	0.06
54	6.42	7.14	0.39	0.15	0.62	0.05
55	6.56	5.46	0.27	0.10	0.61	0.04
Mean	6.515	6.586	0.373	0.099	0.864	0.060
SD	2.556	1.428	0.239	0.032	0.511	0.028
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
76	5.45	6.73	0.73	0.21	0.61	0.03
77	3.84	6.08	0.44	0.10	0.16	0.02
78	4.10	6.02	0.38	0.16	0.57	0.05
79	2.95	4.70	0.38	0.09	0.26	0.02
80	4.81	5.41	0.47	0.10	0.35	0.04
81	3.26	3.24	0.33	0.09	0.23	0.03
82	3.83	3.75	0.30	0.38	0.21	0.04
83	5.38	7.33	0.44	0.13	1.10	0.06
84	3.59	5.61	0.50	0.14	0.97	0.05
85	4.18	8.84	0.41	0.12	0.32	0.05
Mean	4.139	5.771	0.438	0.152	0.478	0.039
SD	0.842	1.657	0.119	0.088	0.330	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
106	4.37	7.85	0.42	0.23	0.51	0.04
107	2.55	6.46	0.27	0.38	0.20	0.03
108	8.72	4.89	0.45	0.28	0.78	0.05
109	4.71	7.14	0.55	0.33	0.36	0.05
110	7.16	6.24	0.47	0.26	0.68	0.05
111	7.20	7.49	0.88	0.46	0.64	0.07
112	2.86	2.79	0.21	0.18	0.15	0.01
113	3.64	4.03	0.33	0.22	0.29	0.02
114	7.84	8.41	0.44	0.36	0.39	0.07
115	6.34	4.52	0.41	0.38	0.29	0.03
Mean	5.539	5.982	0.443	0.308	0.429	0.042
SD	2.191	1.845	0.183	0.088	0.214	0.020
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
136	7.07	5.49	0.37	0.32	0.65	0.04
137	10.93	6.49	0.68	0.72	1.33	0.08
138	4.64	6.25	0.40	0.51	0.23	0.03
139	7.28	7.57	0.52	0.54	0.34	0.05
140	6.75	5.83	0.42	0.50	0.99	0.05
141	6.78	3.49	0.33	0.51	0.38	0.02
142	5.70	5.39	0.37	0.19	0.30	0.04
143	6.93	6.85	0.18	0.58	0.53	0.05
144	8.18	5.52	0.39	0.64	0.92	0.05
145	5.32	5.77	0.38	0.57	0.60	0.02
Mean	6.958	5.865	0.404	0.508	0.627	0.043
SD	1.735	1.083	0.129	0.152	0.354	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
196	7.47	7.22	0.33	0.60	0.92	0.04
197	6.01	6.18	0.17	0.46	0.53	0.04
198	11.39	5.94	0.51	0.65	0.44	0.05
199	7.50	6.01	0.34	0.65	0.67	0.04
200	8.31	4.14	0.31	0.56	0.66	0.03
201	9.83	5.16	0.14	0.68	0.51	0.05
202	5.72	5.80	0.23	0.81	0.40	0.03
203	6.64	7.32	0.39	0.35	0.64	0.04
204	7.44	9.91	0.49	0.75	0.39	0.06
205	3.38	4.06	0.14	0.22	0.19	0.01
Mean	7.369	6.174	0.305	0.573	0.535	0.039
SD	2.215	1.707	0.135	0.182	0.200	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
176	0.63	4.73	0.12	0.08	0.05	0.02
177	0.96	3.88	0.13	0.15	0.03	0.01
178	0.48	3.88	0.13	0.06	0.06	0.01
179	1.33	6.18	0.32	0.12	0.07	0.02
180	0.61	3.25	0.10	0.11	0.04	0.01
Mean	0.802	4.384	0.160	0.104	0.050	0.014
SD	0.344	1.134	0.090	0.035	0.016	0.005
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
26	0.95	6.87	0.22	0.06	0.08	0.02
27	1.21	4.04	0.12	0.22	0.03	0.01
28	1.10	5.12	0.25	0.10	0.10	0.02
29	1.00	3.73	0.19	0.32	0.04	0.01
30	0.43	3.80	0.15	0.15	0.05	0.01
Mean	0.938	4.712	0.186	0.170	0.060	0.014
SD	0.301	1.330	0.052	0.103	0.029	0.005
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
56	1.19	5.93	0.21	0.12	0.08	0.03
57	1.06	5.99	0.13	0.17	0.10	0.02
58	1.00	6.35	0.22	0.09	0.13	0.01
59	0.69	2.56	0.07	0.05	0.03	0.01
60	1.94	9.24	0.37	0.17	0.10	0.04
Mean	1.176	6.014	0.200	0.120	0.088	0.022
SD	0.465	2.369	0.113	0.052	0.037	0.013
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
86	0.87	5.84	0.17	0.06	0.08	0.01
87	1.12	8.33	0.34	0.10	0.12	0.03
88	1.35	6.00	0.32	0.18	0.09	0.02
89	0.86	4.46	0.13	0.06	0.04	0.01
90	0.84	3.20	0.15	0.23	0.03	0.00
Mean	1.008	5.566	0.222	0.126	0.072	0.014
SD	0.223	1.919	0.100	0.076	0.037	0.011
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
116	1.23	2.97	0.11	0.23	0.03	0.01
117	1.49	6.42	0.28	0.11	0.13	0.01
118	1.56	9.16	0.31	0.24	0.14	0.04
119	0.78	3.10	0.15	0.08	0.05	0.00
120	1.28	6.03	0.25	0.13	0.05	0.02
Mean	1.268	5.536	0.220	0.158	0.080	0.016
SD	0.306	2.583	0.086	0.073	0.051	0.015
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
146	1.11	5.98	0.27	0.13	0.06	0.02
147	1.05	3.59	0.18	0.06	0.04	0.00
148	1.32	3.90	0.15	0.09	0.05	0.01
149	1.08	8.46	0.23	0.16	0.10	0.02
150	1.24	4.44	0.23	0.09	0.07	0.01
Mean	1.160	5.274	0.212	0.106	0.064	0.012
SD	0.115	2.004	0.047	0.039	0.023	0.008
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
206	1.21	4.67	0.15	0.20	0.07	0.01
207	1.45	6.95	0.21	0.14	0.09	0.02
208	1.18	8.01	0.25	0.15	0.08	0.02
209	0.67	2.69	0.10	0.06	0.03	0.01
210	1.61	5.19	0.13	0.15	0.05	0.03
Mean	1.224	5.502	0.168	0.140	0.064	0.018
SD	0.357	2.067	0.061	0.050	0.024	0.008
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
16	53.1	1.15	21.59
17	55.4	1.17	21.20
18	57.2	1.19	20.87
19	55.4	1.16	21.04
20	55.5	1.19	21.40
26	55.8	1.19	21.25
27	56.4	1.17	20.81
28	52.4	1.12	21.31
29	55.1	1.17	21.20
30	51.0	1.08	21.22
Mean	54.73	1.159	21.189
SD	1.93	0.035	0.234
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
46	56.3	1.19	21.16
47	54.9	1.17	21.31
48	56.9	1.19	21.01
49	54.0	1.14	21.07
50	54.7	1.18	21.63
56	56.5	1.18	20.96
57	54.1	1.17	21.59
58	55.7	1.18	21.21
59	56.2	1.19	21.24
60	55.0	1.17	21.22
Mean	55.43	1.176	21.240
SD	1.03	0.015	0.223
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
76	52.9	1.14	21.55
77	53.5	1.14	21.35
78	56.2	1.22	21.65
79	53.8	1.18	21.94
80	53.5	1.15	21.42
86	51.9	1.14	21.91
87	56.1	1.18	21.07
88	53.8	1.16	21.55
89	55.0	1.19	21.69
90	54.6	1.20	21.93
Mean	54.13	1.170	21.606
SD	1.36	0.028	0.281
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
106	57.9	1.21	20.89
107	54.2	1.13	20.92
108	54.2	1.15	21.20
109	58.0	1.23	21.29
110	56.5	1.18	20.91
116	56.2	1.18	21.05
117	53.5	1.10	20.60
118	53.9	1.14	21.16
119	54.2	1.17	21.57
120	53.5	1.13	21.10
Mean	55.21	1.162	21.069
SD	1.77	0.040	0.264
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
136	51.6	1.07	20.75
137	54.1	1.15	21.20
138	52.2	1.14	21.84
139	52.8	1.12	21.26
140	54.0	1.16	21.45
146	53.1	1.12	21.11
147	54.6	1.16	21.27
148	56.9	1.22	21.38
149	52.4	1.13	21.50
150	51.8	1.11	21.43
Mean	53.35	1.138	21.319
SD	1.61	0.039	0.284
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
166	53.5	1.18	21.97
167	56.0	1.22	21.81
168	51.3	1.11	21.59
169	52.5	1.13	21.55
170	52.0	1.16	22.33
176	53.9	1.16	21.60
177	51.6	1.11	21.50
178	54.1	1.16	21.37
179	56.1	1.22	21.69
180	51.5	1.13	21.97
Mean	53.25	1.158	21.738
SD	1.78	0.040	0.286
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
196	53.4	1.16	21.80
197	54.2	1.17	21.66
198	51.7	1.12	21.56
199	55.4	1.18	21.29
200	51.8	1.13	21.92
206	52.8	1.31	24.71
207	53.0	1.13	21.24
208	49.4	1.06	21.46
209	52.5	1.13	21.54
210	56.0	1.18	21.15
Mean	53.02	1.157	21.833
SD	1.91	0.065	1.040
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
166	8.9	18.9	272.0	53.9	1.18	21.95
167	9.4	17.7	314.0	55.1	1.19	21.55
168	9.1	17.9	295.0	50.5	1.09	21.56
169	9.4	19.3	247.0	52.6	1.13	21.39
170	9.4	19.3	256.0	51.9	1.13	21.74
171	10.1	19.1	243.0	52.3	1.14	21.73
172	9.4	19.1	283.0	53.7	1.17	21.86
173	9.6	19.4	261.0	48.8	1.07	21.89
174	9.9	18.6	246.0	51.6	1.13	21.85
175	9.2	17.5	256.0	54.4	1.17	21.48
Mean	9.44	18.68	267.30	52.48	1.140	21.700
SD	0.36	0.72	23.49	1.91	0.039	0.193
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
16	9.1	17.7	99.8	54.0	1.13	20.97
17	9.7	14.9	83.3	55.8	1.17	20.99
18	9.1	14.9	88.2	56.8	1.16	20.46
19	8.6	16.8	266.0	54.4	1.15	21.05
20	9.0	14.3	95.0	54.7	1.16	21.12
21	9.4	14.1	86.9	56.1	1.16	20.68
22	8.8	14.9	82.8	51.8	1.09	21.13
23	9.0	15.1	85.9	55.5	1.14	20.54
24	9.3	13.7	93.5	56.2	1.18	20.91
25	8.3	14.4	163.0	55.1	1.15	20.95
Mean	9.03	15.08	114.44	55.04	1.149	20.880
SD	0.40	1.24	58.30	1.43	0.025	0.237
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
46	9.2	17.0	297.0	55.2	1.16	20.99
47	9.6	18.8	327.0	55.7	1.15	20.65
48	9.3	17.6	316.0	57.1	1.17	20.43
49	9.2	16.4	273.0	55.6	1.16	20.81
50	9.8	18.7	325.0	55.7	1.15	20.61
51	9.4	17.1	349.0	53.9	1.12	20.83
52	9.1	19.3	308.0	55.5	1.14	20.61
53	8.6	16.7	308.0	55.3	1.15	20.83
54	8.9	18.2	288.0	53.8	1.12	20.78
55	8.2	16.1	349.0	55.2	1.17	21.23
Mean	9.13	17.59	314.00	55.30	1.149	20.777
SD	0.47	1.11	24.64	0.94	0.018	0.224
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
76	9.6	18.7	258.0	52.9	1.09	20.69
77	9.0	18.7	246.0	53.9	1.12	20.72
78	8.7	17.5	271.0	55.3	1.19	21.50
79	NV !	NV !	NV !	54.9	1.17	21.23
80	9.4	18.5	256.0	51.9	1.11	21.31
81	9.1	17.7	228.0	53.4	1.14	21.44
82	5.3	16.8	441.0	51.2	1.11	21.73
83	9.5	19.6	281.0	50.1	1.09	21.70
84	8.7	21.7	296.0	52.2	1.12	21.52
85	9.0	18.1	241.0	50.0	1.07	21.44
Mean	8.70	18.59	279.78	52.58	1.121	21.328
SD	1.32	1.42	63.93	1.84	0.037	0.362
N	9	9	9	10	10	10

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
106	NV !	NV !	NV !	57.4	1.17	20.38
107	9.4	14.9	250.0	53.2	1.10	20.67
108	9.5	15.4	315.0	53.9	1.10	20.48
109	8.8	14.2	235.0	58.1	1.19	20.53
110	9.1	16.0	306.0	55.8	1.16	20.78
111	9.1	14.8	279.0	52.7	1.10	20.79
112	9.6	14.2	283.0	51.9	1.05	20.31
113	8.9	14.7	275.0	54.2	1.09	20.15
114	9.9	14.9	287.0	53.3	1.10	20.59
115	9.8	13.6	306.0	54.8	1.14	20.86
Mean	9.34	14.74	281.78	54.53	1.120	20.554
SD	0.39	0.70	26.36	2.02	0.043	0.230
N	9	9	9	10	10	10

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
136	9.0	16.9	312.0	50.0	1.06	21.15
137	8.6	14.4	365.0	52.2	1.10	20.97
138	9.0	17.1	247.0	52.2	1.09	20.95
139	8.5	18.1	311.0	52.2	1.09	20.86
140	9.3	17.9	275.0	53.3	1.12	21.08
141	9.5	17.4	304.0	49.6	1.06	21.47
142	9.2	15.8	284.0	53.9	1.14	21.15
143	10.3	19.6	311.0	52.2	1.13	21.54
144	9.3	16.8	312.0	53.0	1.13	21.39
145	9.7	17.5	270.0	50.0	1.08	21.65
Mean	9.24	17.15	299.10	51.86	1.100	21.221
SD	0.53	1.38	32.24	1.49	0.029	0.273
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
196	9.4	17.8	290.0	53.0	1.11	20.95
197	NV !	NV !	NV !	54.1	1.13	20.91
198	9.7	18.0	314.0	52.3	1.08	20.61
199	9.6	16.8	306.0	53.8	1.14	21.12
200	9.3	18.2	293.0	50.6	1.10	21.66
201	9.9	17.0	321.0	54.5	1.16	21.36
202	NV !	NV !	NV !	53.7	1.12	20.78
203	8.5	20.0	272.0	52.2	1.11	21.27
204	9.6	17.1	290.0	53.0	1.11	20.87
205	9.1	17.6	296.0	51.2	1.10	21.45
Mean	9.39	17.81	297.75	52.84	1.116	21.098
SD	0.44	1.01	15.50	1.27	0.023	0.331
N	8	8	8	10	10	10

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
176	9.4	14.2	89.0	52.9	1.10	20.73
177	9.3	15.7	92.0	50.4	1.06	21.04
178	8.7	17.0	156.0	51.8	1.08	20.83
179	8.8	15.1	87.5	53.0	1.14	21.61
180	10.2	14.6	95.5	50.8	1.05	20.75
Mean	9.28	15.32	104.00	51.78	1.086	20.992
SD	0.60	1.09	29.23	1.18	0.036	0.367
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
26	8.9	17.1	91.8	52.9	1.09	20.59
27	9.4	17.9	90.5	54.6	1.12	20.55
28	10.4	NV !	NV !	50.7	1.06	20.83
29	8.9	16.4	93.8	52.3	1.08	20.69
30	9.1	16.8	76.9	49.5	1.04	20.93
Mean	9.34	17.05	88.25	52.00	1.078	20.718
SD	0.63	0.64	7.69	1.97	0.030	0.160
N	5	4	4	5	5	5

! = Result Comment

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
56	9.4	15.1	89.8	54.3	1.10	20.21
57	8.9	NV !	NV !	52.7	1.09	20.65
58	9.3	14.7	89.5	53.7	1.09	20.25
59	9.6	16.3	86.8	55.9	1.13	20.24
60	9.6	16.2	81.0	51.3	1.06	20.66
Mean	9.36	15.58	86.78	53.58	1.094	20.402
SD	0.29	0.80	4.08	1.72	0.025	0.231
N	5	4	4	5	5	5

! = Result Comment

TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
86	9.4	17.1	87.0	50.3	1.05	20.91
87	9.6	16.6	75.3	52.8	1.09	20.69
88	9.1	16.1	83.6	53.4	1.09	20.45
89	9.3	18.1	NM !	53.7	1.11	20.57
90	8.9	19.7	222.0	52.3	1.09	20.91
Mean	9.26	17.52	116.98	52.50	1.086	20.706
SD	0.27	1.43	70.19	1.34	0.022	0.205
N	5	5	4	5	5	5

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
116	8.9	18.7	86.6	52.7	1.09	20.77
117	9.1	15.7	78.9	49.9	1.02	20.55
118	9.2	18.3	142.0	50.1	1.02	20.41
119	9.3	15.4	82.1	53.0	1.11	20.98
120	9.3	16.2	94.6	50.1	1.02	20.46
Mean	9.16	16.86	96.84	51.16	1.052	20.634
SD	0.17	1.53	25.92	1.55	0.044	0.238
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
146	8.7	16.8	89.9	50.9	1.03	20.35
147	8.8	20.4	83.3	54.2	1.10	20.23
148	8.6	17.3	87.3	53.9	1.11	20.60
149	9.2	18.5	99.0	50.0	1.04	20.88
150	9.0	16.9	74.5	51.8	1.06	20.52
Mean	8.86	17.98	86.80	52.16	1.068	20.516
SD	0.24	1.51	8.98	1.84	0.036	0.249
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
206	8.8	15.6	79.8	51.2	1.04	20.31
207	8.9	16.9	76.2	52.0	1.08	20.81
208	8.6	15.7	102.0	48.5	0.99	20.41
209	9.5	17.0	75.1	52.7	1.09	20.69
210	9.0	16.3	90.3	54.0	1.12	20.82
Mean	8.96	16.30	84.68	51.68	1.064	20.608
SD	0.34	0.65	11.39	2.05	0.050	0.235
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
16	8.4	0.73	90.7	10.6	21.7
17	8.4	0.82	77.0	11.1	18.9
18	8.1	0.71	73.7	12.1	21.0
19	7.2	0.70	69.0	11.6	20.4
20	8.1	0.66	86.2	11.0	21.2
26	8.4	0.74	71.1	10.2	19.0
27	6.8	0.73	68.9	10.9	21.7
28	7.3	0.62	78.2	11.0	22.8
29	7.5	0.94	75.3	11.1	19.9
30	7.6	0.92	90.1	11.9	21.6
Mean	7.78	0.757	78.02	11.15	20.82
SD	0.58	0.105	8.25	0.58	1.26
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
46	9.0	0.56	84.2	11.1	22.1
47	7.9	0.66	93.1	11.2	22.2
48	8.2	0.84	90.7	11.6	21.1
49	8.6	0.49	77.1	10.8	22.3
50	8.8	0.53	100.8	10.4	23.6
56	7.9	0.59	89.0	12.2	21.7
57	7.4	0.61	85.9	10.8	21.9
58	8.1	0.59	90.9	11.1	22.2
59	8.5	0.67	77.1	11.8	20.0
60	8.2	0.65	84.9	11.4	21.9
Mean	8.26	0.619	87.37	11.24	21.90
SD	0.48	0.097	7.22	0.53	0.92
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
76	6.7	0.96	85.1	10.7	24.2
77	6.3	0.67	69.7	10.4	23.8
78	7.1	0.91	85.4	11.8	22.0
79	6.9	0.50	94.0	10.3	25.6
80	7.0	0.75	98.0	10.7	24.4
86	7.3	0.63	93.0	10.5	22.6
87	6.5	0.93	72.9	11.3	22.9
88	6.9	0.66	79.3	10.5	22.8
89	7.4	0.68	94.1	11.1	24.0
90	7.1	0.67	73.4	11.4	22.0
Mean	6.92	0.736	84.49	10.87	23.43
SD	0.34	0.150	10.23	0.50	1.16
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
106	7.6	0.82	77.2	13.2	22.0
107	7.6	0.70	86.9	11.8	21.8
108	7.0	0.66	80.2	11.5	23.2
109	7.6	0.96	80.5	12.1	20.5
110	8.1	0.85	73.5	11.4	20.1
116	7.2	0.72	67.5	11.4	21.3
117	8.1	0.66	87.8	12.0	21.2
118	9.2	0.80	86.1	12.5	21.0
119	7.7	0.69	85.7	11.0	22.1
120	8.4	0.84	84.1	11.6	21.4
Mean	7.85	0.770	80.95	11.85	21.46
SD	0.63	0.099	6.60	0.64	0.88
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
136	7.0	0.61	83.4	12.7	23.7
137	7.1	0.78	64.7	10.3	22.7
138	7.0	0.68	87.0	11.9	24.5
139	7.1	0.82	81.0	11.7	22.9
140	7.0	0.68	91.8	10.8	24.8
146	7.7	0.66	85.7	11.3	23.4
147	6.4	0.77	80.9	10.7	23.7
148	7.5	0.79	80.2	11.9	23.4
149	7.5	0.90	91.3	12.6	23.8
150	7.2	0.79	97.7	12.2	25.1
Mean	7.15	0.748	84.37	11.61	23.80
SD	0.36	0.088	8.93	0.82	0.78
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
166	7.4	0.67	79.5	11.3	23.0
167	7.4	0.60	83.9	11.4	22.7
168	6.7	0.78	91.6	11.9	24.7
169	7.0	0.86	83.8	11.3	22.4
170	6.6	0.60	84.0	10.8	22.9
176	7.6	0.74	90.8	10.9	23.4
177	7.2	0.75	70.1	10.7	21.5
178	7.7	0.62	94.9	11.5	23.8
179	6.7	0.77	86.0	12.3	24.1
180	7.6	0.77	100.3	11.6	24.3
Mean	7.19	0.716	86.49	11.37	23.28
SD	0.41	0.089	8.46	0.50	0.97
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
196	6.9	0.66	82.2	10.2	23.7
197	7.3	0.72	90.5	12.0	24.5
198	7.5	0.69	89.5	10.8	25.6
199	7.2	0.73	65.7	11.7	21.9
200	6.6	0.64	76.3	10.2	24.2
206	7.7	0.67	94.9	11.1	24.0
207	6.5	0.66	71.0	10.5	25.0
208	8.0	0.77	83.9	12.0	22.9
209	7.4	0.93	93.5	11.7	23.6
210	7.4	0.86	78.4	12.4	23.7
Mean	7.25	0.733	82.59	11.26	23.91
SD	0.47	0.095	9.77	0.81	1.04
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
166	8.4	0.47	97.8	13.3	24.1
167	9.1	0.49	105.4	12.4	23.1
168	8.5	0.56	99.7	12.2	23.7
169	8.6	0.66	98.3	12.6	22.5
170	8.0	0.46	101.8	11.9	23.7
171	7.8	0.39	92.1	10.7	22.5
172	11.3	0.33	93.7	12.8	23.3
173	8.6	0.40	99.6	11.6	25.2
174	7.9	0.44	107.4	11.3	23.7
175	8.2	0.64	99.4	12.9	23.9
Mean	8.64	0.484	99.52	12.17	23.57
SD	1.01	0.107	4.66	0.80	0.79
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
16	11.1	1.08	56.3	15.1	18.8
17	12.0	1.52	57.8	15.3	15.8
18	10.6	0.98	54.2	14.1	18.6
19	10.3	1.14	57.5	14.3	17.4
20	10.6	0.94	57.4	13.4	18.0
21	10.7	0.99	58.9	13.7	17.3
22	10.4	1.22	56.4	14.6	18.9
23	10.9	1.13	54.2	14.2	16.8
24	10.6	1.24	59.1	13.8	18.7
25	10.6	1.32	54.5	14.0	17.4
Mean	10.78	1.156	56.63	14.25	17.77
SD	0.48	0.177	1.84	0.60	1.01
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
46	11.8	0.54	74.0	16.0	20.2
47	11.8	0.61	65.4	16.1	18.7
48	11.0	1.01	63.8	15.7	18.8
49	13.5	0.54	70.1	17.2	20.6
50	12.9	0.68	70.4	16.5	20.6
51	11.1	0.75	63.6	15.1	19.2
52	14.3	0.89	81.6	16.0	21.1
53	10.9	0.86	67.6	15.0	19.6
54	11.0	0.73	67.1	14.8	19.4
55	11.0	0.72	61.8	15.9	19.0
Mean	11.93	0.733	68.54	15.83	19.72
SD	1.22	0.153	5.88	0.73	0.85
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
76	9.1	0.84	81.6	13.1	20.0
77	8.3	0.71	74.1	13.7	19.1
78	8.4	0.75	75.4	13.3	18.9
79	9.4	0.46	83.8	14.4	20.3
80	9.1	0.58	93.5	12.5	21.4
81	8.6	0.50	83.2	12.9	20.5
82	8.2	0.69	94.0	12.7	20.9
83	11.4	0.67	80.8	12.8	20.6
84	8.1	0.42	76.2	12.1	21.5
85	8.7	0.57	84.6	12.6	20.2
Mean	8.93	0.619	82.72	13.01	20.34
SD	0.97	0.135	6.86	0.66	0.86
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
106	10.7	1.09	61.3	15.2	19.0
107	10.2	0.82	62.9	14.5	19.3
108	10.3	0.95	69.2	15.9	20.4
109	10.4	0.97	53.7	15.2	17.8
110	10.2	1.00	61.0	14.7	19.9
111	10.3	0.91	58.3	14.6	19.5
112	9.8	0.81	67.1	15.0	20.8
113	10.6	0.64	57.0	14.4	18.9
114	11.7	1.02	63.5	16.3	19.9
115	11.3	1.03	58.7	15.4	17.8
Mean	10.55	0.924	61.27	15.12	19.33
SD	0.56	0.134	4.66	0.62	1.00
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
136	8.7	0.70	86.6	14.5	21.9
137	9.0	0.65	74.2	12.7	21.4
138	8.8	0.66	70.5	13.9	20.1
139	9.7	0.54	89.9	14.1	20.2
140	9.3	0.55	81.9	13.5	21.1
141	9.0	0.74	82.8	11.9	20.8
142	8.8	0.53	80.9	12.8	21.2
143	11.2	0.62	94.9	12.8	23.3
144	10.0	0.85	90.3	13.9	21.3
145	8.9	0.70	90.6	12.9	22.3
Mean	9.34	0.654	84.26	13.30	21.36
SD	0.78	0.100	7.72	0.80	0.96
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
196	8.9	0.71	76.4	14.5	21.1
197	9.1	0.69	75.6	14.9	20.7
198	9.5	0.77	81.2	13.2	21.8
199	8.8	0.58	74.1	13.5	20.4
200	10.0	0.66	93.1	13.5	22.6
201	9.5	0.71	91.2	12.9	21.6
202	9.5	0.56	79.8	12.7	19.4
203	8.6	0.65	79.3	12.6	20.4
204	8.8	0.79	72.2	12.7	20.3
205	12.6	0.45	83.6	13.2	21.9
Mean	9.53	0.657	80.65	13.37	21.02
SD	1.16	0.103	6.96	0.78	0.96
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
176	7.9	0.96	67.5	12.9	20.7
177	7.7	0.77	64.4	12.9	19.9
178	9.0	0.75	79.2	13.2	20.4
179	7.9	0.78	87.9	12.5	22.3
180	7.4	0.82	62.0	13.3	20.5
Mean	7.98	0.816	72.20	12.96	20.76
SD	0.61	0.084	10.98	0.31	0.91
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
26	8.8	0.88	62.8	10.9	18.2
27	8.0	0.81	61.6	11.7	18.5
28	9.2	0.47	68.5	12.1	17.6
29	8.2	1.02	63.9	11.3	18.0
30	8.3	0.83	74.7	12.2	19.3
Mean	8.50	0.802	66.30	11.64	18.32
SD	0.49	0.203	5.37	0.55	0.64
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
56	8.2	0.93	66.7	13.1	18.6
57	8.1	0.75	63.5	12.8	18.2
58	7.9	0.80	60.7	13.6	20.2
59	9.1	0.75	68.4	14.2	18.0
60	8.9	0.71	75.0	13.2	19.5
Mean	8.44	0.788	66.86	13.38	18.90
SD	0.53	0.086	5.43	0.54	0.93
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
86	7.3	0.73	72.1	12.7	20.7
87	7.4	0.98	64.3	12.6	19.8
88	8.2	0.72	72.3	14.5	20.7
89	9.1	0.87	75.4	13.4	19.5
90	8.4	0.69	77.2	12.5	19.6
Mean	8.08	0.798	72.26	13.14	20.06
SD	0.75	0.123	4.94	0.84	0.59
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
116	8.0	0.66	74.4	12.7	20.0
117	9.2	0.77	77.4	13.4	18.9
118	9.3	0.86	72.3	12.7	19.4
119	7.8	0.59	68.0	13.2	20.1
120	9.0	0.69	73.7	13.4	19.0
Mean	8.66	0.714	73.16	13.08	19.48
SD	0.71	0.104	3.43	0.36	0.55
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
146	8.3	0.60	69.9	13.4	19.7
147	7.8	0.85	63.0	13.2	19.0
148	7.5	0.60	60.3	13.1	20.3
149	7.3	0.67	89.8	13.4	23.2
150	7.8	0.74	76.4	13.7	21.0
Mean	7.74	0.692	71.88	13.36	20.64
SD	0.38	0.106	11.82	0.23	1.61
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
206	6.9	0.55	67.1	13.0	21.8
207	7.9	0.75	70.6	13.1	21.0
208	8.2	0.85	75.3	13.6	21.6
209	7.6	0.81	71.4	13.4	20.8
210	8.2	0.94	77.3	13.7	19.6
Mean	7.76	0.780	72.34	13.36	20.96
SD	0.54	0.146	4.02	0.30	0.86
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	HGB	Quality Flag	I (Include)
	10	6	Male	152	RBC	Quality Flag	I (Include)
	10	6	Male	152	WBC	Quality Flag	I (Include)
	10	6	Male	152	Reticulocyte (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Reticulocyte (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	PLT	Quality Flag	I (Include)
	10	6	Male	152	HCT	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	Neutrophils (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Lymphocytes (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Monocytes (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Eosinophils (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Large Uncla Cells Rel	Quality Flag	I (Include)
	10	6	Male	152	Basophils (Relative)	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	Neutrophils (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Lymphocytes (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Monocytes (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Eosinophils (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Large Unclas sified Cells	Quality Flag	I (Include)
	10	6	Male	152	Basophils (Absolute)	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	MCV	Quality Flag	I (Include)
	10	6	Male	152	MCH	Quality Flag	I (Include)
	10	6	Male	152	MCHC	Quality Flag	I (Include)
	17	1	Male	2	PT	Replacement	NV
			Comment:	Sample clotted			
	17	1	Male	2	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	1	Male	2	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	3	Male	62	PT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Male	62	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Male	62	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	MPV	Quality Flag	I (Include)
	10	6	Male	152	Plateletcrit	Quality Flag	I (Include)
	10	6	Male	152	Platlet Dist Width	Quality Flag	I (Include)
	10	6	Male	152	RDW	Quality Flag	I (Include)
	10	6	Male	152	MPC	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	3	Female	79	PT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Female	79	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Female	79	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	4	Female	106	PT	Replacement	NV
			Comment:	Sample clotted			
	17	4	Female	106	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	4	Female	106	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	197	PT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	197	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	197	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	202	PT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	202	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	202	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	38	1	Female	28	aPTT	Replacement	NV
			Comment:	Sample clotted			
	38	1	Female	28	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	38	2	Female	57	aPTT	Replacement	NV
			Comment:	Sample clotted			
	38	2	Female	57	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	38	3	Female	89	Fibrinogen	Replacement	NM
			Comment:	No Measurement			

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a1]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a2]	Glucose (mmol/L) [a2]
Group 1: Control	Mean	29.48	27.12	1.087	3.71	1.982	39.6	9.142
	SD	0.68	0.71	0.029	0.70	0.371	2.1	0.548
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	26.70**	29.70**	0.901**	3.24	1.611*	37.6	8.973
	SD	0.41	1.56	0.045	0.46	0.348	2.1	0.493
	N	10	10	10	10	10	10	10
	%Diff	-9.4	9.5	-17.1	-12.7	-18.7	-5.1	-1.8
Group 3: 10 µg/ animal BNT162a1	Mean	27.48**	27.62	0.996**	2.72**	1.730	43.2**	6.324**
	SD	0.70	0.99	0.036	0.39	0.265	2.5	0.663
	N	10	10	10	10	10	10	10
	%Diff	-6.8	1.8	-8.4	-26.7	-12.7	9.1	-30.8
Group 4: 30 µg/ animal BNT162b1	Mean	28.27**	31.43**	0.902**	3.26	1.647	39.7	8.610
	SD	0.62	1.98	0.042	0.44	0.233	1.6	0.443
	N	10	10	10	10	10	10	10
	%Diff	-4.1	15.9	-17.1	-12.1	-16.9	0.3	-5.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	27.41**	29.59**	0.929**	2.70**	1.458**	43.5**	6.074**
100 µg/	SD	0.63	1.87	0.051	0.24	0.358	3.1	0.703
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-7.0	9.1	-14.6	-27.2	-26.4	9.8	-33.6
Group 6:	Mean	27.22**	28.88*	0.944**	2.64**	1.598*	42.5**	6.837**
30 µg/	SD	0.44	1.04	0.038	0.23	0.225	4.5	1.050
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-7.7	6.5	-13.2	-28.8	-19.4	7.3	-25.2
Group 7:	Mean	26.79**	29.11*	0.923**	2.78**	1.478**	43.6*	6.753**
100 µg/	SD	0.86	1.83	0.051	0.32	0.221	4.6	1.946
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-9.1	7.3	-15.1	-25.1	-25.4	10.1	-26.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	27.32 n	28.08 n	0.975 n	3.12 n	1.227 n	44.6 n	8.840 n
	SD	0.87	1.60	0.042	0.39	0.191	4.0	1.072
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Cholesterol (total) (mmol/L) [a2]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 1: Control	Mean	28.34	25.36	1.119	2.38	1.894	46.0	9.517
	SD	1.08	1.40	0.048	0.26	0.369	2.4	1.289
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	26.78**	27.82**	0.963**	3.34**	1.184**	47.0	8.263
	SD	0.61	1.08	0.026	0.28	0.293	4.0	1.061
	N	10	10	10	10	10	10	10
	%Diff	-5.5	9.7	-13.9	40.3	-37.5	2.2	-13.2
Group 3: 10 µg/ animal BNT162a1	Mean	26.67**	27.03	0.988**	3.13**	1.485*	48.4	8.385
	SD	0.84	1.39	0.037	0.40	0.202	2.0	0.884
	N	10	10	10	10	10	10	10
	%Diff	-5.9	6.6	-11.7	31.5	-21.6	5.2	-11.9
Group 4: 30 µg/ animal BNT162b1	Mean	27.23**	30.07**	0.908**	2.86	1.135**	47.1	8.697
	SD	0.66	1.72	0.048	0.28	0.164	2.1	0.945
	N	10	10	10	10	10	10	10
	%Diff	-3.9	18.6	-18.9	20.2	-40.1	2.4	-8.6

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	27.26**	32.04**	0.853**	3.48**	1.298**	50.6**	8.165
100 µg/	SD	0.70	1.77	0.044	0.75	0.246	3.2	1.205
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-3.8	26.3	-23.8	46.2	-31.5	10.0	-14.2
Group 7:	Mean	26.68**	31.22**	0.856**	3.40**	1.290**	51.5**	8.930
100 µg/	SD	0.47	1.29	0.029	0.36	0.147	3.7	0.918
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-5.9	23.1	-23.6	42.9	-31.9	12.0	-6.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	27.92 n	27.88 n	1.002 n	3.04 n	1.518 n	49.8 n	9.060 n
	SD	0.72	0.87	0.034	0.11	0.066	2.3	1.876
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 1: Control	Mean	28.88	27.32	1.057	2.96	1.478	48.0	9.988
	SD	0.92	0.53	0.038	0.55	0.184	2.7	2.833
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	28.44	26.96	1.057	3.10	1.706	48.8	10.420
	SD	0.84	1.27	0.054	0.59	0.429	2.2	1.641
	N	5	5	5	5	5	5	5
	%Diff	-1.5	-1.3	-0.1	4.7	15.4	1.7	4.3
Group 3: 10 µg/ animal BNT162a1	Mean	28.40	25.00	1.137	2.94	1.664	48.8	10.504
	SD	0.92	0.92	0.063	0.36	0.249	1.9	0.898
	N	5	5	5	5	5	5	5
	%Diff	-1.7	-8.5	7.6	-0.7	12.6	1.7	5.2
Group 4: 30 µg/ animal BNT162b1	Mean	28.34	28.66	0.994	2.54	1.818	53.2**	9.794
	SD	0.76	2.42	0.083	0.38	0.269	1.3	1.207
	N	5	5	5	5	5	5	5
	%Diff	-1.9	4.9	-6.0	-14.2	23.0	10.8	-1.9

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	28.46	24.94	1.150	2.76	1.646	50.0	10.282
100 µg/	SD	0.78	2.59	0.112	0.30	0.183	3.5	1.654
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.5	-8.7	8.8	-6.8	11.4	4.2	2.9
Group 7:	Mean	29.14	27.66	1.057	2.88	1.908	48.6	9.008
100 µg/	SD	0.51	1.67	0.070	0.13	0.288	1.7	0.858
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	0.9	1.2	-0.1	-2.7	29.1	1.3	-9.8

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a1]	Tri-glycerides (mmol/L) [a2]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a1]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a1]
Group 1: Control	Mean	2.563	56.6	1.911	5.954	2.824	100.9	4.393
	SD	0.165	1.2	0.680	0.858	0.058	0.7	0.307
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	2.555	56.4	1.127**	6.670	2.798	101.0	4.478
	SD	0.081	1.8	0.400	0.444	0.084	0.9	0.274
	N	10	10	10	10	10	10	10
	%Diff	-0.3	-0.4	-41.0	12.0	-0.9	0.1	1.9
Group 3: 10 µg/ animal BNT162a1	Mean	2.695	55.1	0.573**	7.432	2.635**	102.1**	3.984**
	SD	0.136	1.4	0.170	1.467	0.076	0.7	0.190
	N	10	10	10	10	10	10	10
	%Diff	5.2	-2.7	-70.0	24.8	-6.7	1.2	-9.3
Group 4: 30 µg/ animal BNT162b1	Mean	2.338*	59.7**	1.504	6.626	2.842	101.0	4.411
	SD	0.144	2.5	0.360	0.739	0.061	0.7	0.224
	N	10	10	10	10	10	10	10
	%Diff	-8.8	5.5	-21.3	11.3	0.6	0.1	0.4

[a] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett: ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.609	57.0	0.507**	7.586	2.639**	103.0**	3.925**
100 µg/	SD	0.087	2.3	0.236	1.408	0.107	0.5	0.217
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	1.8	0.7	-73.5	27.4	-6.6	2.1	-10.7
Group 6:	Mean	2.622	56.1	0.565**	6.660	2.567**	102.9**	4.315
30 µg/	SD	0.204	1.1	0.197	0.812	0.097	0.9	0.239
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	2.3	-0.9	-70.4	11.9	-9.1	2.0	-1.8
Group 7:	Mean	2.569	55.9	0.507**	7.298	2.632**	103.0**	4.043*
100 µg/	SD	0.225	2.4	0.162	1.831	0.137	1.2	0.283
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	0.2	-1.2	-73.5	22.6	-6.8	2.1	-8.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	2.571 n	55.4 n	0.456 n	8.006 n	2.575 n	99.0 n	3.987 n
	SD	0.163	2.3	0.115	0.595	0.086	1.4	0.223
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a1]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a1]
Group 1: Control	Mean	2.245	53.7	0.413	6.968	2.546	100.6	3.904
	SD	0.295	2.2	0.139	0.751	0.088	1.4	0.390
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	2.658**	54.6	0.509	8.386**	2.621	100.4	4.182
	SD	0.329	1.6	0.163	0.947	0.090	1.7	0.390
	N	10	10	10	10	10	10	10
	%Diff	18.4	1.7	23.2	20.4	2.9	-0.2	7.1
Group 3: 10 µg/ animal BNT162a1	Mean	2.416	53.7	0.540	8.267*	2.512	99.8	3.959
	SD	0.213	2.1	0.073	1.117	0.073	1.2	0.132
	N	10	10	10	10	10	10	10
	%Diff	7.6	0.0	30.8	18.6	-1.3	-0.8	1.4
Group 4: 30 µg/ animal BNT162b1	Mean	2.145	57.3**	0.368	7.457	2.556	100.6	4.141
	SD	0.265	2.1	0.094	1.596	0.098	1.6	0.527
	N	10	10	10	10	10	10	10
	%Diff	-4.5	6.7	-10.9	7.0	0.4	0.0	6.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.324	59.3**	0.545	8.536**	2.579	100.4	4.073
100 µg/	SD	0.286	2.1	0.160	1.115	0.066	1.5	0.391
animal	N	9	10	10	10	10	10	9
BNT162b1	%Diff	3.5	10.4	32.0	22.5	1.3	-0.2	4.3
Group 7:	Mean	2.365	57.9**	0.478	9.437**	2.607	100.1	4.220
100 µg/	SD	0.245	1.6	0.124	1.246	0.068	0.7	0.342
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	5.3	7.8	15.7	35.4	2.4	-0.5	8.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	2.120 n	55.8 n	0.466 n	6.506 n	2.414 n	103.8 n	4.242 n
	SD	0.571	1.3	0.170	0.397	0.083	0.8	0.950
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a2]	Potassium (mmol/L) [a]
Group 1: Control	Mean	2.138	56.2	0.498	6.770	2.546	103.2	3.922
	SD	0.150	1.1	0.075	1.318	0.110	0.8	0.229
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	2.192	55.4	0.476	7.182	2.540	102.0	4.068
	SD	0.227	1.7	0.163	0.582	0.082	1.0	0.083
	N	5	5	5	5	5	5	5
	%Diff	2.5	-1.4	-4.4	6.1	-0.2	-1.2	3.7
Group 3: 10 µg/ animal BNT162a1	Mean	2.116	53.4	0.428	7.546	2.482	102.8	3.944
	SD	0.281	1.1	0.158	0.909	0.055	1.3	0.417
	N	5	5	5	5	5	5	5
	%Diff	-1.0	-5.0	-14.1	11.5	-2.5	-0.4	0.6
Group 4: 30 µg/ animal BNT162b1	Mean	2.100	57.0	0.568	7.636	2.464	103.2	3.892
	SD	0.207	2.7	0.070	1.044	0.070	1.3	0.179
	N	5	5	5	5	5	5	5
	%Diff	-1.8	1.4	14.1	12.8	-3.2	0.0	-0.8

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Log)
[a2] - Anova & Dunnett(Rank)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.160	53.4	0.538	7.690	2.502	103.0	4.062
100 µg/	SD	0.288	2.9	0.195	1.256	0.064	1.0	0.136
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	1.0	-5.0	8.0	13.6	-1.7	-0.2	3.6
Group 7:	Mean	2.194	56.8	0.712	7.494	2.522	104.0	4.042
100 µg/	SD	0.116	1.5	0.182	1.460	0.052	1.0	0.167
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	2.6	1.1	43.0	10.7	-0.9	0.8	3.1

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a1]	aP (U/L) [a2]	ASAT (U/L) [a1]	LDH (U/L) [a]	CK (U/L) [a1]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	135.2	66.1	270.2	80.3	90.0	127.2	0.95
	SD	0.8	16.7	53.3	13.4	18.9	26.6	0.87
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	135.4	56.9	257.9	85.1	68.6	176.7	4.21**
	SD	1.0	7.7	32.8	3.9	18.5	72.5	0.96
	N	10	10	10	10	10	10	10
	%Diff	0.1	-13.9	-4.6	6.0	-23.8	38.9	343.2
Group 3: 10 µg/ animal BNT162a1	Mean	136.6**	48.8**	181.8**	99.5**	117.5	120.0	2.93**
	SD	0.8	7.1	50.3	8.5	25.6	93.1	0.51
	N	10	10	10	10	10	10	10
	%Diff	1.0	-26.2	-32.7	23.9	30.6	-5.7	208.4
Group 4: 30 µg/ animal BNT162b1	Mean	135.9	61.9	257.5	77.3	81.5	216.6	2.52**
	SD	0.6	8.7	32.2	6.0	26.0	110.3	0.54
	N	10	10	10	10	10	10	10
	%Diff	0.5	-6.4	-4.7	-3.7	-9.4	70.3	165.3

[a] - Anova & Dunnett: ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a2] - Anova & Dunnett(Log): ** = p ≤ 0.01

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	137.3**	45.6**	195.0**	87.0	126.5*	132.7	3.32**
100 µg/	SD	0.7	8.2	27.4	9.3	43.1	96.4	0.65
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	1.6	-31.0	-27.8	8.3	40.6	4.3	249.5
Group 6:	Mean	136.8**	44.2**	189.8**	95.4**	134.9**	152.7	3.60**
30 µg/	SD	0.9	4.0	24.3	6.7	35.0	48.9	1.09
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	1.2	-33.1	-29.8	18.8	49.9	20.0	278.9
Group 7:	Mean	137.3**	44.4**	209.9**	95.9**	138.7**	155.1	3.25**
100 µg/	SD	0.8	9.3	27.2	9.0	39.1	64.8	1.09
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	1.6	-32.8	-22.3	19.4	54.1	21.9	242.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	132.1 n	49.5 n	160.3 n	110.4 n	124.6 n	152.6 n	3.98 n
	SD	1.4	4.6	13.9	9.9	25.5	53.9	1.12
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a1]	LDH (U/L) [a1]	CK (U/L) [a]	Gamma-GT (U/L) [a1]
Group 1: Control	Mean	134.7	35.9	157.2	79.9	109.5	158.0	1.62
	SD	0.9	8.0	25.5	15.6	49.9	106.7	0.76
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	133.8	40.1	190.6*	101.3**	134.0	165.6	4.43**
	SD	2.0	8.2	29.1	12.9	38.8	56.6	0.70
	N	10	10	10	10	10	10	10
	%Diff	-0.7	11.7	21.2	26.8	22.4	4.8	173.5
Group 3: 10 µg/ animal BNT162a1	Mean	133.1*	38.9	133.1	93.8	124.1	124.7	3.04**
	SD	1.1	6.6	28.5	17.3	44.2	22.9	0.90
	N	10	10	10	10	10	10	10
	%Diff	-1.2	8.4	-15.3	17.4	13.3	-21.1	87.7
Group 4: 30 µg/ animal BNT162b1	Mean	134.4	36.2	140.4	88.7	103.4	154.2	3.59**
	SD	1.6	3.2	22.3	8.2	29.5	38.4	0.56
	N	10	10	10	10	10	10	10
	%Diff	-0.2	0.8	-10.7	11.0	-5.6	-2.4	121.6

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05
[a1] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	132.4**	37.9	164.3	85.4	119.6	146.0	4.18**
100 µg/	SD	2.5	13.7	25.3	8.7	24.4	42.1	1.00
animal	N	10	10	10	9	9	10	10
BNT162b1	%Diff	-1.7	5.6	4.5	6.9	9.2	-7.6	158.0
Group 7:	Mean	132.7**	34.0	182.1	89.1	124.3	126.4	4.83**
100 µg/	SD	0.5	6.0	37.1	9.7	20.1	16.3	0.81
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-1.5	-5.3	15.8	11.5	13.5	-20.0	198.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	138.4 n	44.0 n	129.8 n	86.2 n	120.4 n	143.4 n	1.84 n
	SD	1.1	6.2	12.9	14.3	24.5	64.4	0.47
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a1]	LDH (U/L) [a1]	CK (U/L) [a1]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	136.6	34.6	110.8	80.4	113.4	305.0	2.60
	SD	0.9	3.0	17.9	20.1	60.0	454.5	0.91
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	135.6	35.4	117.8	78.2	96.6	220.8	2.74
	SD	1.1	3.8	6.9	3.8	42.3	165.0	0.66
	N	5	5	5	5	5	5	5
	%Diff	-0.7	2.3	6.3	-2.7	-14.8	-27.6	5.4
Group 3: 10 µg/ animal BNT162a1	Mean	138.2	37.0	107.6	86.6	132.6	173.6	1.88
	SD	1.1	3.2	24.3	13.2	59.6	131.2	0.54
	N	5	5	5	5	5	5	5
	%Diff	1.2	6.9	-2.9	7.7	16.9	-43.1	-27.7
Group 4: 30 µg/ animal BNT162b1	Mean	137.8	40.4	133.0	87.6	72.4	125.6	2.30
	SD	2.2	3.0	28.5	5.9	44.9	79.5	0.50
	N	5	5	5	5	5	5	5
	%Diff	0.9	16.8	20.0	9.0	-36.2	-58.8	-11.5

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	137.8	40.0	126.4	88.8	105.6	235.6	1.34
100 µg/	SD	1.3	4.1	22.3	14.3	50.4	87.7	0.86
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	0.9	15.6	14.1	10.4	-6.9	-22.8	-48.5
Group 7:	Mean	138.4	39.8	117.4	82.6	74.2	199.8	1.82
100 µg/	SD	0.9	6.5	22.3	10.9	4.1	155.9	0.97
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	1.3	15.0	6.0	2.7	-34.6	-34.5	-30.0

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a2]	Glucose (mmol/L) [a2]
Group 1: Control	Mean	31.61	27.69	1.144	3.51	1.865	43.4	9.037
	SD	1.45	1.71	0.062	0.76	0.309	2.3	0.940
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	27.15**	28.95	0.938**	3.68	1.989	42.1	8.935
	SD	1.06	1.09	0.033	0.65	0.388	1.9	0.737
	N	10	10	10	10	10	10	10
	%Diff	-14.1	4.6	-18.0	4.8	6.6	-3.0	-1.1
Group 3: 10 µg/ animal BNT162a1	Mean	28.03**	25.67	1.095	2.79*	2.062	44.4	6.889**
	SD	1.01	1.82	0.057	0.37	0.275	3.2	1.362
	N	10	10	10	10	10	10	10
	%Diff	-11.3	-7.3	-4.3	-20.5	10.6	2.3	-23.8
Group 4: 30 µg/ animal BNT162b1	Mean	28.97**	30.33*	0.958**	2.57**	1.931	42.6	8.841
	SD	0.93	1.65	0.057	0.40	0.245	1.0	0.731
	N	10	10	10	10	10	10	10
	%Diff	-8.4	9.5	-16.3	-26.8	3.5	-1.8	-2.2

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	28.21**	29.89	0.950**	2.77**	1.865	43.1	7.267
100 µg/	SD	0.69	2.80	0.072	0.37	0.441	3.3	1.698
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-10.8	7.9	-17.0	-21.1	0.0	-0.7	-19.6
Group 6:	Mean	27.92**	27.28	1.028**	3.07	1.948	44.2	7.362*
30 µg/	SD	0.66	2.12	0.072	0.34	0.336	2.1	1.562
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-11.7	-1.5	-10.1	-12.5	4.5	1.8	-18.5
Group 7:	Mean	27.62**	28.68	0.964**	2.73**	1.853	42.8	6.521**
100 µg/	SD	0.97	1.62	0.029	0.39	0.220	2.8	1.059
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-12.6	3.6	-15.7	-22.2	-0.6	-1.4	-27.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	27.35 n	26.15 n	1.049 n	3.03 n	1.632 n	46.5 n	8.044 n
	SD	0.64	1.70	0.052	0.20	0.246	3.3	0.582
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a1]	Alb./Glob. Ratio [a2]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 1: Control	Mean	30.36	25.54	1.192	3.03	1.764	46.8	9.502
	SD	1.12	1.57	0.069	0.53	0.389	3.5	0.829
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	27.68**	29.02**	0.962**	4.04**	1.818	47.9	7.820**
	SD	0.84	3.23	0.083	0.55	0.349	2.6	0.873
	N	10	10	10	10	10	10	10
	%Diff	-8.8	13.6	-19.3	33.3	3.1	2.4	-17.7
Group 3: 10 µg/ animal BNT162a1	Mean	27.69**	25.81	1.076	3.61	1.894	49.2	8.533
	SD	0.71	1.50	0.073	0.51	0.384	2.5	1.076
	N	10	10	10	10	10	10	10
	%Diff	-8.8	1.1	-9.7	19.1	7.4	5.1	-10.2
Group 4: 30 µg/ animal BNT162b1	Mean	27.38**	30.12**	0.910**	3.06	1.448	47.2	8.614
	SD	1.04	1.72	0.037	0.57	0.284	1.8	1.551
	N	10	10	10	10	10	10	10
	%Diff	-9.8	17.9	-23.6	1.0	-17.9	0.9	-9.3

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	27.17**	29.23**	0.933**	3.83*	1.444	49.3	8.167*
	SD	1.05	2.34	0.054	0.72	0.322	2.6	1.046
	N	10	10	10	10	10	10	10
	%Diff	-10.5	14.4	-21.7	26.4	-18.1	5.3	-14.0
Group 7: 100 µg/ animal BNT162b2	Mean	27.03**	30.07**	0.901**	3.96*	1.305*	50.2*	8.487
	SD	0.69	1.68	0.044	0.97	0.159	3.1	1.241
	N	10	10	10	10	10	10	10
	%Diff	-11.0	17.7	-24.4	30.7	-26.0	7.3	-10.7

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	31.10 n	28.50 n	1.092 n	3.46 n	1.640 n	52.8 n	9.506 n
	SD	1.53	1.38	0.041	0.57	0.498	4.2	0.880
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a1]	Glucose (mmol/L) [a]
Group 1: Control	Mean	31.26	29.54	1.058	2.78	1.878	55.2	9.136
	SD	2.25	0.55	0.077	0.19	0.453	2.9	1.348
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	30.96	30.64	1.011	3.38	1.952	52.4	8.822
	SD	1.90	1.69	0.051	1.07	0.638	3.8	1.369
	N	5	5	5	5	5	5	5
	%Diff	-1.0	3.7	-4.5	21.6	3.9	-5.1	-3.4
Group 3: 10 µg/ animal BNT162a1	Mean	29.76	23.84**	1.251**	3.26	1.626	51.0	9.618
	SD	0.56	1.30	0.069	0.30	0.342	1.7	1.414
	N	5	5	5	5	5	5	5
	%Diff	-4.8	-19.3	18.2	17.3	-13.4	-7.6	5.3
Group 4: 30 µg/ animal BNT162b1	Mean	30.80	30.00	1.029	3.00	1.780	54.8	10.114
	SD	0.79	1.71	0.053	0.39	0.124	3.7	1.512
	N	5	5	5	5	5	5	5
	%Diff	-1.5	1.6	-2.8	7.9	-5.2	-0.7	10.7

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	30.88	27.72	1.118	3.14	1.804	55.2	10.164
100 µg/	SD	1.97	2.85	0.067	0.54	0.596	5.9	2.126
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.2	-6.2	5.7	12.9	-3.9	0.0	11.3
Group 7:	Mean	30.50	27.10	1.132	2.86	2.038	51.2	9.334
100 µg/	SD	0.96	2.03	0.115	0.33	0.321	2.9	2.048
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	-2.4	-8.3	7.0	2.9	8.5	-7.2	2.2

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 1: Control	Mean	2.207	59.3	1.560	6.913	2.770	102.2	4.244
	SD	0.225	2.8	0.602	0.943	0.089	1.2	0.257
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	2.487*	56.1*	1.846	6.966	2.815	100.7**	4.118
	SD	0.183	1.9	0.538	0.775	0.064	1.1	0.190
	N	10	10	10	10	10	10	10
	%Diff	12.7	-5.4	18.3	0.8	1.6	-1.5	-3.0
Group 3: 10 µg/ animal BNT162a1	Mean	2.278	53.7**	0.521**	6.622	2.640**	103.3	3.844*
	SD	0.231	2.6	0.109	1.299	0.104	0.8	0.216
	N	10	10	10	10	10	10	10
	%Diff	3.2	-9.4	-66.6	-4.2	-4.7	1.1	-9.4
Group 4: 30 µg/ animal BNT162b1	Mean	2.329	59.3	0.906**	6.964	2.818	101.7	4.226
	SD	0.110	1.9	0.334	0.795	0.083	0.9	0.309
	N	10	10	10	10	10	10	10
	%Diff	5.5	0.0	-41.9	0.7	1.7	-0.5	-0.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): ** = $p \leq 0.01$

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.321	58.1	0.534**	6.604	2.724	103.3	4.040
100 µg/	SD	0.234	3.3	0.211	1.059	0.115	0.8	0.381
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	5.2	-2.0	-65.8	-4.5	-1.7	1.1	-4.8
Group 6:	Mean	2.536**	55.2**	0.678**	6.935	2.709	102.5	4.006
30 µg/	SD	0.236	2.5	0.248	1.262	0.085	1.0	0.214
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	14.9	-6.9	-56.5	0.3	-2.2	0.3	-5.6
Group 7:	Mean	2.355	56.3	0.441**	6.147	2.694	103.3	3.980
100 µg/	SD	0.167	2.5	0.187	0.594	0.072	1.2	0.316
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	6.7	-5.1	-71.7	-11.1	-2.7	1.1	-6.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	2.236 n	53.5 n	0.453 n	8.592 n	2.597 n	100.2 n	4.019 n
	SD	0.167	2.2	0.105	0.687	0.087	1.8	0.285
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 1: Control	Mean	1.845	55.9	0.340	7.863	2.574	101.9	3.590
	SD	0.300	2.2	0.095	1.373	0.111	1.0	0.336
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	2.246**	56.7	0.475*	7.850	2.666	100.8	3.899
	SD	0.237	3.8	0.136	1.322	0.100	1.7	0.259
	N	10	10	10	10	10	10	10
	%Diff	21.7	1.4	39.7	-0.2	3.6	-1.1	8.6
Group 3: 10 µg/ animal BNT162a1	Mean	2.043	53.5	0.603**	8.094	2.587	102.3	3.996*
	SD	0.228	1.6	0.225	1.122	0.104	1.2	0.190
	N	10	10	10	10	10	10	10
	%Diff	10.7	-4.3	77.4	2.9	0.5	0.4	11.3
Group 4: 30 µg/ animal BNT162b1	Mean	2.124	57.5	0.357	8.105	2.663	101.3	3.902
	SD	0.272	2.6	0.070	0.857	0.099	0.8	0.246
	N	10	10	10	10	10	10	10
	%Diff	15.1	2.9	5.0	3.1	3.5	-0.6	8.7

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.088	56.4	0.444	8.453	2.640	101.4	4.180**
100 µg/	SD	0.347	3.3	0.104	1.284	0.084	1.3	0.378
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	13.2	0.9	30.6	7.5	2.6	-0.5	16.4
Group 7:	Mean	2.039	57.1	0.450	8.324	2.685	102.4	3.954*
100 µg/	SD	0.202	2.1	0.109	1.162	0.076	1.3	0.346
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	10.5	2.1	32.4	5.9	4.3	0.5	10.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.700 n	59.6 n	0.396 n	7.398 n	2.522 n	102.2 n	3.530 n
	SD	0.209	2.7	0.146	1.166	0.086	0.8	0.126
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a1]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a1]	Calcium (mmol/L) [a1]	Chloride (mmol/L) [a1]	Potassium (mmol/L) [a1]
Group 1: Control	Mean	1.630	60.8	0.408	8.010	2.584	103.2	3.504
	SD	0.192	2.4	0.107	0.743	0.078	1.8	0.347
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	1.786	61.6	0.406	7.682	2.546	103.6	3.426
	SD	0.153	3.2	0.053	1.402	0.068	1.5	0.336
	N	5	5	5	5	5	5	5
	%Diff	9.6	1.3	-0.5	-4.1	-1.5	0.4	-2.2
Group 3: 10 µg/ animal BNT162a1	Mean	1.830	53.6**	0.418	8.366	2.476	102.4	3.750
	SD	0.196	1.5	0.071	0.562	0.056	1.1	0.120
	N	5	5	5	5	5	5	5
	%Diff	12.3	-11.8	2.5	4.4	-4.2	-0.8	7.0
Group 4: 30 µg/ animal BNT162b1	Mean	1.780	60.8	0.348	8.390	2.586	103.2	3.574
	SD	0.065	2.2	0.073	0.946	0.088	0.8	0.304
	N	5	5	5	5	5	5	5
	%Diff	9.2	0.0	-14.7	4.7	0.1	0.0	2.0

[a] - Anova & Dunnett(Rank)
[a1] - Anova & Dunnett: ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	1.776	58.6	0.484	7.230	2.490	102.6	3.522
100 µg/	SD	0.403	4.6	0.208	1.054	0.130	0.9	0.319
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	9.0	-3.6	18.6	-9.7	-3.6	-0.6	0.5
Group 7:	Mean	1.908	57.6	0.396	7.528	2.510	103.2	3.580
100 µg/	SD	0.416	1.8	0.081	0.733	0.111	1.5	0.418
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	17.1	-5.3	-2.9	-6.0	-2.9	0.0	2.2

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a1]	aP (U/L) [a1]	ASAT (U/L) [a1]	LDH (U/L) [a2]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	135.8	57.3	154.2	74.5	86.1	118.0	0.88
	SD	1.0	7.6	24.9	19.2	18.8	44.8	0.59
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	135.0	59.1	198.0**	85.8	68.7	133.6	3.67**
	SD	1.2	7.4	35.9	10.7	10.0	79.3	1.10
	N	10	10	10	10	10	10	10
	%Diff	-0.6	3.1	28.4	15.2	-20.2	13.2	317.0
Group 3: 10 µg/ animal BNT162a1	Mean	136.8	45.5*	141.7	98.8**	120.3	153.4	2.75**
	SD	1.0	9.7	20.2	9.8	48.7	112.3	0.54
	N	10	10	10	10	10	10	10
	%Diff	0.7	-20.6	-8.1	32.6	39.7	30.0	212.5
Group 4: 30 µg/ animal BNT162b1	Mean	135.4	49.0	167.7	75.8	67.6	129.7	2.32
	SD	0.8	13.0	22.3	11.6	13.9	71.8	1.01
	N	10	10	10	10	10	10	10
	%Diff	-0.3	-14.5	8.8	1.7	-21.5	9.9	163.6

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	136.7	40.1**	150.6	90.7*	125.0*	119.0	3.72**
100 µg/	SD	1.1	7.6	25.7	10.4	44.3	140.6	1.48
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	0.7	-30.0	-2.3	21.7	45.2	0.8	322.7
Group 6:	Mean	135.7	52.1	151.5	107.2**	142.9**	136.7	3.77**
30 µg/	SD	0.9	9.5	25.9	9.9	38.5	130.2	0.78
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-0.1	-9.1	-1.8	43.9	66.0	15.8	328.4
Group 7:	Mean	136.8	36.4**	161.3	96.6**	133.3*	106.1	4.01**
100 µg/	SD	1.5	7.7	24.5	13.8	49.2	69.8	0.85
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	0.7	-36.5	4.6	29.7	54.8	-10.1	355.7

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	132.3 n	58.1 n	141.7 n	122.5 n	108.6 n	122.2 n	4.26 n
	SD	2.0	27.4	32.1	15.8	18.1	23.4	0.79
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a1]	ASAT (U/L) [a1]	LDH (U/L) [a1]	CK (U/L) [a]	Gamma-GT (U/L) [a1]
Group 1: Control	Mean	134.9	34.2	75.9	80.6	125.3	106.6	1.21
	SD	0.7	7.0	11.7	10.6	40.6	31.1	0.59
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	133.1*	57.8**	155.9**	118.7**	141.7	175.7	3.97**
	SD	1.1	26.2	23.2	21.8	40.2	131.6	0.72
	N	10	10	10	10	10	10	10
	%Diff	-1.3	69.0	105.4	47.3	13.1	64.8	228.1
Group 3: 10 µg/ animal BNT162a1	Mean	134.1	37.9	120.5**	95.3	155.9	182.3	3.32**
	SD	1.7	5.9	25.5	12.6	26.7	125.9	1.33
	N	10	10	10	10	10	10	10
	%Diff	-0.6	10.8	58.8	18.2	24.4	71.0	174.4
Group 4: 30 µg/ animal BNT162b1	Mean	133.4	34.3	108.7*	86.4	104.6	165.0	3.94**
	SD	1.3	6.4	24.5	13.0	38.7	107.7	1.10
	N	10	10	10	10	10	10	10
	%Diff	-1.1	0.3	43.2	7.2	-16.5	54.8	225.6

[a] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	132.6**	33.4	158.9**	102.7**	147.4	183.7	4.40**
100 µg/	SD	2.1	6.8	29.6	9.9	40.1	92.6	0.61
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-1.7	-2.3	109.4	27.4	17.6	72.3	263.6
Group 7:	Mean	133.8	30.8	183.8**	100.2*	155.4	139.6	5.05**
100 µg/	SD	1.9	6.7	24.6	12.5	61.5	31.8	0.88
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-0.8	-9.9	142.2	24.3	24.0	31.0	317.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	136.4 n	32.0 n	68.4 n	86.6 n	118.0 n	250.6 n	2.14 n
	SD	1.1	10.0	14.0	24.7	13.6	255.4	0.33
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a1]	aP (U/L) [a1]	ASAT (U/L) [a2]	LDH (U/L) [a2]	CK (U/L) [a2]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	136.8	35.4	61.4	79.2	69.4	120.2	2.48
	SD	2.4	7.1	13.3	7.6	37.5	45.2	0.76
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	137.4	40.6	67.4	94.8	90.0	205.0	3.06
	SD	2.1	20.0	20.8	45.7	72.9	263.1	0.65
	N	5	5	5	5	5	5	5
	%Diff	0.4	14.7	9.8	19.7	29.7	70.5	23.4
Group 3: 10 µg/ animal BNT162a1	Mean	136.0	32.4	72.4	79.4	132.6	315.4	1.74
	SD	1.0	4.2	7.5	14.0	38.1	368.0	0.86
	N	5	5	5	5	5	5	5
	%Diff	-0.6	-8.5	17.9	0.3	91.1	162.4	-29.8
Group 4: 30 µg/ animal BNT162b1	Mean	136.6	30.4	64.6	84.6	100.2	208.4	2.52
	SD	0.5	7.3	2.5	15.3	53.1	101.2	0.67
	N	5	5	5	5	5	5	5
	%Diff	-0.1	-14.1	5.2	6.8	44.4	73.4	1.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)
[a2] - Anova & Dunnett(Log)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	137.0	35.4	64.8	85.4	108.4	165.4	2.12
100 µg/	SD	0.7	3.4	14.3	20.3	60.2	108.1	0.64
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	0.1	0.0	5.5	7.8	56.2	37.6	-14.5
Group 7:	Mean	137.8	31.6	67.0	82.2	89.0	151.8	2.44
100 µg/	SD	1.6	5.4	5.1	10.7	49.4	59.4	0.66
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	0.7	-10.7	9.1	3.8	28.2	26.3	-1.6

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	Cholesterol (total)	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Bilirubin (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Creatinine	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Glucose	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	4	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Cholesterol (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Creatinine	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Globulin	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Cholesterol (total)	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	Creatinine	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Globulin	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	7	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Choleste- rol (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Crea- tinine	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Male	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Bilirubin (total)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Choleste- rol (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Bilirubin (total)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Choleste- rol (total)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	4	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Choleste- rol (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	5	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Choleste- rol (total)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Male	Crea- tinine	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Choleste- rol (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Crea- tinine	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	38	4	Male	Crea- tinine	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Chloride	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Potassium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	Phosphate	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	4	4	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Potassium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	10	6	Male	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Phosphate	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Urea	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Urea	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	4	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Urea	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Urea	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	ALAT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	aP	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	ASAT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Lactate Dehy drogenase	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Lactate Dehy drogenase	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Lactate Dehy drogenase	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	aP	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	2	Male	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Sodium	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	3	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Bilirubin (total)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	3	Female	Glucose	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	4	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Globulin	*	Anova & Dunnett: * = p ≤ 0.05
	4	4	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Bilirubin (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Glucose	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	Alb./Glob. Ratio	**	Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Alb./Glob. Ratio	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Bilirubin (total)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Glucose	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Bilirubin (total)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Choleste- rol (total)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Crea- tinine	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	38	3	Female	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Phosphate	*	Anova & Dunnett: * = p ≤ 0.05
	4	2	Female	Protein (total)	*	Anova & Dunnett: * = p ≤ 0.05
	4	2	Female	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Female	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	4	4	Female	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Phosphate	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Phosphate	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Tri- glycerides	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	3	Female	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Potassium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	31	6	Female	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics
	38	3	Female	Protein (total)	**	Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Gamma-GT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Female	ALAT	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Gamma-GT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	5	Female	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	ASAT	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Female	Lactate Dehy drogenase	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Lactate Dehy drogenase	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Lactate Dehy drogenase	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Sodium	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	2	Female	ALAT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	3	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	aP	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	ASAT	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
1	28.6	25.4	1.13	3.2	1.54	39	9.22
2	29.4	26.6	1.11	3.0	2.05	38	8.95
3	30.1	27.9	1.08	4.7	2.03	40	8.55
4	29.6	27.4	1.08	4.7	2.30	45	9.42
5	30.1	26.9	1.12	4.0	2.54	40	8.61
11	29.4	27.6	1.07	2.6	1.54	39	9.74
12	28.5	27.5	1.04	3.9	1.94	39	10.16
13	30.5	27.5	1.11	4.0	2.37	40	8.85
14	29.8	27.2	1.10	3.8	1.46	39	9.41
15	28.8	27.2	1.06	3.2	2.05	37	8.51
Mean	29.48	27.12	1.087	3.71	1.982	39.6	9.142
SD	0.68	0.71	0.029	0.70	0.371	2.1	0.548
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
31	27.2	29.8	0.91	2.8	1.47	41	8.96
32	26.1	29.9	0.87	3.7	1.07	35	8.63
33	26.5	26.5	1.00	3.0	1.94	37	9.26
34	26.9	29.1	0.92	3.7	1.31	36	8.77
35	26.6	30.4	0.88	3.9	1.36	41	9.25
41	27.2	30.8	0.88	2.9	1.65	39	8.63
42	27.0	31.0	0.87	3.0	1.42	36	10.02
43	26.1	28.9	0.90	3.7	1.95	36	9.27
44	26.9	32.1	0.84	2.6	2.20	37	8.29
45	26.5	28.5	0.93	3.1	1.74	38	8.65
Mean	26.70	29.70	0.901	3.24	1.611	37.6	8.973
SD	0.41	1.56	0.045	0.46	0.348	2.1	0.493
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
61	26.7	27.3	0.98	2.5	1.82	41	6.40
62	27.6	27.4	1.01	2.2	1.88	48	5.50
63	26.2	25.8	1.02	2.1	1.52	42	5.93
64	27.4	29.6	0.93	2.8	1.58	42	7.50
65	28.3	27.7	1.02	3.3	1.85	42	5.86
71	27.6	28.4	0.97	3.1	1.25	40	6.85
72	27.0	28.0	0.96	3.1	1.97	45	6.19
73	27.5	27.5	1.00	2.6	2.18	44	6.17
74	28.3	27.7	1.02	2.8	1.56	42	7.19
75	28.2	26.8	1.05	2.7	1.69	46	5.65
Mean	27.48	27.62	0.996	2.72	1.730	43.2	6.324
SD	0.70	0.99	0.036	0.39	0.265	2.5	0.663
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
91	27.6	31.4	0.88	3.4	1.54	40	8.08
92	27.7	29.3	0.95	2.7	1.23	39	8.15
93	28.0	31.0	0.90	3.0	1.55	39	8.58
94	29.0	36.0	0.81	3.6	1.73	39	8.11
95	28.4	31.6	0.90	3.9	1.76	39	9.10
101	28.6	30.4	0.94	3.4	1.50	43	8.89
102	29.4	33.6	0.88	3.5	1.94	39	8.80
103	27.5	30.5	0.90	2.5	2.02	39	8.34
104	28.1	29.9	0.94	3.0	1.71	42	9.38
105	28.4	30.6	0.93	3.6	1.49	38	8.67
Mean	28.27	31.43	0.902	3.26	1.647	39.7	8.610
SD	0.62	1.98	0.042	0.44	0.233	1.6	0.443
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
121	28.2	28.8	0.98	3.0	1.35	47	6.06
122	26.9	29.1	0.92	2.5	0.93	38	7.00
123	27.1	31.9	0.85	2.9	2.07	42	4.83
124	27.9	31.1	0.90	2.2	1.73	45	5.42
125	27.6	27.4	1.01	2.8	1.22	47	5.79
131	27.3	29.7	0.92	2.8	1.33	45	5.97
132	28.2	32.8	0.86	2.9	1.97	45	6.04
133	26.1	26.9	0.97	2.5	1.24	40	5.94
134	27.5	29.5	0.93	2.6	1.46	41	6.45
135	27.3	28.7	0.95	2.8	1.28	45	7.24
Mean	27.41	29.59	0.929	2.70	1.458	43.5	6.074
SD	0.63	1.87	0.051	0.24	0.358	3.1	0.703
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
151	27.3	29.7	0.92	2.7	1.98	45	6.24
152	27.4	27.6	0.99	2.6	1.79	43	7.46
153	27.0	30.0	0.90	2.7	1.71	46	5.58
154	27.9	28.1	0.99	3.0	1.49	43	6.00
155	27.2	30.8	0.88	2.6	1.50	42	5.75
161	26.6	28.4	0.94	2.3	1.82	31	7.79
162	26.5	28.5	0.93	2.3	1.63	42	6.13
163	27.6	28.4	0.97	2.9	1.39	46	7.38
164	27.6	29.4	0.94	2.8	1.39	46	8.80
165	27.1	27.9	0.97	2.5	1.28	41	7.24
Mean	27.22	28.88	0.944	2.64	1.598	42.5	6.837
SD	0.44	1.04	0.038	0.23	0.225	4.5	1.050
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
181	26.7	30.3	0.88	2.7	1.45	44	6.30
182	27.8	31.2	0.89	2.6	1.50	45	10.82
183	27.6	30.4	0.91	2.5	1.48	42	9.75
184	25.7	27.3	0.94	3.4	1.78	55	5.18
185	27.4	28.6	0.96	2.8	1.63	39	5.93
191	25.0	28.0	0.89	2.6	1.38	40	5.44
192	26.6	26.4	1.01	2.6	1.00	39	5.14
193	27.2	27.8	0.98	2.5	1.42	44	5.87
194	26.9	32.1	0.84	3.3	1.39	45	6.65
195	27.0	29.0	0.93	2.8	1.75	43	6.45
Mean	26.79	29.11	0.923	2.78	1.478	43.6	6.753
SD	0.86	1.83	0.051	0.32	0.221	4.6	1.946
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
151	27.5	28.5	0.96	3.1	1.38	42	9.19
152	28.3	29.7	0.95	3.0	1.22	53	10.89
153	28.0	30.0	0.93	2.6	1.61	46	8.04
154	28.0	27.0	1.04	3.7	1.14	47	7.94
155	27.0	29.0	0.93	2.8	1.26	43	9.30
156	27.9	30.1	0.93	3.3	1.31	40	7.41
157	27.8	27.2	1.02	3.4	1.08	48	10.06
158	26.7	27.3	0.98	3.1	0.88	40	8.09
159	25.6	26.4	0.97	2.6	1.19	44	9.08
160	26.4	25.6	1.03	3.6	1.20	43	8.40
Mean	27.32	28.08	0.975	3.12	1.227	44.6	8.840
SD	0.87	1.60	0.042	0.39	0.191	4.0	1.072
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
1	29.1	25.9	1.12	2.7	1.33	42	9.92
2	28.7	24.3	1.18	2.4	1.72	47	10.93
3	28.7	28.3	1.01	2.0	1.69	48	10.07
4	28.6	25.4	1.13	2.3	2.03	47	8.77
5	29.8	25.2	1.18	2.3	2.46	43	7.56
6	28.1	25.9	1.08	2.1	1.99	47	7.31
7	29.1	25.9	1.12	2.4	2.44	43	9.40
8	26.5	23.5	1.13	2.9	1.92	49	10.03
9	26.5	23.5	1.13	2.3	1.90	48	11.16
10	28.3	25.7	1.10	2.4	1.46	46	10.02
Mean	28.34	25.36	1.119	2.38	1.894	46.0	9.517
SD	1.08	1.40	0.048	0.26	0.369	2.4	1.289
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
31	27.2	27.8	0.98	3.3	1.23	46	7.75
32	26.8	29.2	0.92	3.0	0.98	47	5.81
33	27.2	28.8	0.94	3.0	1.23	42	8.58
34	26.7	27.3	0.98	3.6	0.96	45	9.28
35	26.3	26.7	0.99	3.5	1.20	44	9.60
36	27.9	29.1	0.96	3.6	1.86	54	8.70
37	26.9	28.1	0.96	2.9	0.81	53	8.07
38	25.6	26.4	0.97	3.4	0.96	43	7.78
39	26.6	28.4	0.94	3.4	1.31	48	8.93
40	26.6	26.4	1.01	3.7	1.30	48	8.13
Mean	26.78	27.82	0.963	3.34	1.184	47.0	8.263
SD	0.61	1.08	0.026	0.28	0.293	4.0	1.061
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
61	26.6	27.4	0.97	3.2	1.48	48	8.34
62	28.1	27.9	1.01	2.6	1.61	52	7.49
63	25.5	25.5	1.00	3.4	1.18	49	7.83
64	26.7	29.3	0.91	3.0	1.48	48	9.64
65	27.4	26.6	1.03	2.7	1.32	49	8.88
66	27.1	27.9	0.97	3.8	1.29	48	7.25
67	25.5	24.5	1.04	3.3	1.53	46	8.39
68	27.3	27.7	0.99	2.6	1.68	49	8.59
69	26.5	27.5	0.96	3.4	1.87	45	7.59
70	26.0	26.0	1.00	3.3	1.41	50	9.85
Mean	26.67	27.03	0.988	3.13	1.485	48.4	8.385
SD	0.84	1.39	0.037	0.40	0.202	2.0	0.884
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
91	26.3	28.7	0.92	3.1	1.10	46	8.49
92	27.2	26.8	1.01	2.2	1.07	47	9.02
93	26.6	29.4	0.90	2.8	1.07	46	7.40
94	28.5	32.5	0.88	2.7	1.12	48	8.59
95	26.6	29.4	0.90	2.8	1.13	50	8.47
96	27.9	29.1	0.96	3.1	1.01	44	9.38
97	27.6	30.4	0.91	3.1	1.06	49	10.63
98	27.3	31.7	0.86	2.8	1.09	50	7.82
99	27.0	31.0	0.87	3.0	1.11	46	7.83
100	27.3	31.7	0.86	3.0	1.59	45	9.34
Mean	27.23	30.07	0.908	2.86	1.135	47.1	8.697
SD	0.66	1.72	0.048	0.28	0.164	2.1	0.945
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
121	28.2	30.8	0.92	3.9	1.08	53	6.01
122	27.0	30.0	0.90	3.5	0.79	46	7.66
123	26.4	31.6	0.84	3.1	1.67	51	7.87
124	26.5	33.5	0.79	2.5	1.15	47	8.61
125	26.2	29.8	0.88	3.0	1.33	52	8.45
126	27.3	31.7	0.86	3.2	1.29	55	8.82
127	27.8	31.2	0.89	3.2	1.46	49	10.62
128	27.5	32.5	0.85	3.5	1.45	50	8.56
129	27.9	35.1	0.79	3.6	1.47	55	7.10
130	27.8	34.2	0.81	5.3	1.29	48	7.95
Mean	27.26	32.04	0.853	3.48	1.298	50.6	8.165
SD	0.70	1.77	0.044	0.75	0.246	3.2	1.205
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
181	26.6	30.4	0.88	3.0	1.14	53	9.45
182	27.0	30.0	0.90	3.9	1.47	57	7.51
183	27.1	33.9	0.80	3.4	1.35	52	10.14
184	26.5	30.5	0.87	3.1	1.25	56	8.01
185	26.0	31.0	0.84	2.8	1.37	51	9.16
186	27.1	32.9	0.82	3.5	1.09	53	8.80
187	26.7	31.3	0.85	3.8	1.20	49	7.92
188	27.3	31.7	0.86	3.5	1.24	52	10.13
189	26.6	30.4	0.88	3.7	1.23	46	9.54
190	25.9	30.1	0.86	3.3	1.56	46	8.64
Mean	26.68	31.22	0.856	3.40	1.290	51.5	8.930
SD	0.47	1.29	0.029	0.36	0.147	3.7	0.918
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
161	28.8	28.2	1.02	3.1	1.44	49	9.70
162	26.9	28.1	0.96	3.0	1.62	51	9.23
163	27.6	26.4	1.05	3.2	1.51	47	9.46
164	28.3	28.7	0.99	3.0	1.53	53	5.93
165	28.0	28.0	1.00	2.9	1.49	49	10.98
Mean	27.92	27.88	1.002	3.04	1.518	49.8	9.060
SD	0.72	0.87	0.034	0.11	0.066	2.3	1.876
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
11	29.5	27.5	1.07	3.1	1.28	49	12.51
12	28.3	26.7	1.06	3.7	1.47	48	7.21
13	28.9	28.1	1.03	3.1	1.73	52	13.33
14	30.0	27.0	1.11	2.7	1.33	46	9.47
15	27.7	27.3	1.01	2.2	1.58	45	7.42
Mean	28.88	27.32	1.057	2.96	1.478	48.0	9.988
SD	0.92	0.53	0.038	0.55	0.184	2.7	2.833
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
41	29.5	28.5	1.04	3.9	1.89	48	8.57
42	28.5	26.5	1.08	2.7	1.09	46	13.02
43	27.2	26.8	1.01	2.4	1.81	52	10.36
44	28.2	27.8	1.01	3.1	2.23	49	9.66
45	28.8	25.2	1.14	3.4	1.51	49	10.49
Mean	28.44	26.96	1.057	3.10	1.706	48.8	10.420
SD	0.84	1.27	0.054	0.59	0.429	2.2	1.641
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
71	29.8	24.2	1.23	3.4	1.48	52	9.97
72	28.3	24.7	1.15	3.0	1.58	47	9.98
73	27.4	25.6	1.07	3.0	2.03	48	9.77
74	27.8	24.2	1.15	2.4	1.80	49	10.89
75	28.7	26.3	1.09	2.9	1.43	48	11.91
Mean	28.40	25.00	1.137	2.94	1.664	48.8	10.504
SD	0.92	0.92	0.063	0.36	0.249	1.9	0.898
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
101	29.0	27.0	1.07	3.1	1.41	54	11.07
102	28.5	30.5	0.93	2.5	1.77	54	10.38
103	27.4	29.6	0.93	2.2	2.15	54	8.69
104	29.1	30.9	0.94	2.7	1.91	53	8.33
105	27.7	25.3	1.09	2.2	1.85	51	10.50
Mean	28.34	28.66	0.994	2.54	1.818	53.2	9.794
SD	0.76	2.42	0.083	0.38	0.269	1.3	1.207
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
131	28.0	28.0	1.00	2.9	1.38	50	9.82
132	28.9	23.1	1.25	2.4	1.76	53	10.51
133	27.5	23.5	1.17	2.5	1.76	54	12.17
134	29.5	27.5	1.07	2.9	1.80	47	7.76
135	28.4	22.6	1.26	3.1	1.53	46	11.15
Mean	28.46	24.94	1.150	2.76	1.646	50.0	10.282
SD	0.78	2.59	0.112	0.30	0.183	3.5	1.654
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
191	28.5	30.5	0.93	2.7	2.01	49	8.71
192	29.8	27.2	1.10	3.0	1.73	46	8.65
193	29.5	27.5	1.07	3.0	2.10	50	10.43
194	29.0	27.0	1.07	2.8	1.50	50	8.17
195	28.9	26.1	1.11	2.9	2.20	48	9.08
Mean	29.14	27.66	1.057	2.88	1.908	48.6	9.008
SD	0.51	1.67	0.070	0.13	0.288	1.7	0.858
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
1	2.60	54	1.25	6.59	2.77	101	4.34
2	2.79	56	1.54	5.82	2.74	100	4.31
3	2.65	58	2.54	7.06	2.90	100	4.02
4	2.41	57	3.33	4.78	2.87	101	4.72
5	2.44	57	1.63	6.41	2.83	100	4.65
11	2.62	57	1.38	4.85	2.80	101	3.79
12	2.71	56	1.55	7.05	2.74	102	4.49
13	2.50	58	2.58	5.56	2.88	102	4.29
14	2.24	57	1.42	6.30	2.85	101	4.64
15	2.67	56	1.89	5.12	2.86	101	4.68
Mean	2.563	56.6	1.911	5.954	2.824	100.9	4.393
SD	0.165	1.2	0.680	0.858	0.058	0.7	0.307
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
31	2.60	57	0.80	7.45	2.76	102	4.45
32	2.61	56	1.28	6.11	2.79	101	4.50
33	2.50	53	1.36	6.06	2.89	100	4.12
34	2.62	56	1.55	6.55	2.84	101	4.10
35	2.68	57	1.26	6.75	2.70	100	4.67
41	2.54	58	0.61	6.80	2.87	102	4.62
42	2.47	58	0.78	6.97	2.92	100	4.85
43	2.42	55	1.77	6.98	2.70	102	4.85
44	2.50	59	1.23	6.19	2.69	100	4.39
45	2.61	55	0.63	6.84	2.82	102	4.23
Mean	2.555	56.4	1.127	6.670	2.798	101.0	4.478
SD	0.081	1.8	0.400	0.444	0.084	0.9	0.274
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
61	3.04	54	0.44	6.26	2.68	101	4.14
62	2.59	55	0.52	4.77	2.64	103	4.05
63	2.63	52	0.39	7.36	2.49	102	3.80
64	2.60	57	0.64	8.01	2.60	102	4.15
65	2.70	56	0.90	6.78	2.66	103	3.98
71	2.72	56	0.37	9.46	2.54	102	4.07
72	2.66	55	0.63	8.65	2.64	102	3.79
73	2.56	55	0.72	5.98	2.68	101	3.95
74	2.73	56	0.44	8.69	2.66	102	4.26
75	2.72	55	0.68	8.36	2.76	103	3.65
Mean	2.695	55.1	0.573	7.432	2.635	102.1	3.984
SD	0.136	1.4	0.170	1.467	0.076	0.7	0.190
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
91	2.52	59	1.11	6.35	2.84	101	4.34
92	2.44	57	1.31	5.45	2.76	101	4.20
93	2.32	59	1.23	6.80	2.83	102	4.49
94	2.51	65	1.96	7.20	2.94	100	4.74
95	2.24	60	1.88	6.25	2.86	101	4.27
101	2.22	59	1.34	6.47	2.80	102	4.22
102	2.52	63	2.04	8.19	2.93	100	4.09
103	2.23	58	1.04	5.98	2.76	101	4.46
104	2.17	58	1.65	6.87	2.84	101	4.73
105	2.21	59	1.48	6.70	2.86	101	4.57
Mean	2.338	59.7	1.504	6.626	2.842	101.0	4.411
SD	0.144	2.5	0.360	0.739	0.061	0.7	0.224
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
121	2.63	57	0.74	6.61	2.65	103	3.75
122	2.54	56	0.39	7.29	2.58	103	4.12
123	2.61	59	0.91	4.75	2.67	103	3.68
124	2.76	59	0.80	8.39	2.74	103	3.75
125	2.72	55	0.22	8.56	2.54	104	4.08
131	2.60	57	0.53	7.51	2.77	102	3.59
132	2.56	61	0.50	8.93	2.78	103	3.95
133	2.64	53	0.32	6.51	2.56	103	4.12
134	2.57	57	0.38	7.68	2.65	103	4.22
135	2.46	56	0.28	9.63	2.45	103	3.99
Mean	2.609	57.0	0.507	7.586	2.639	103.0	3.925
SD	0.087	2.3	0.236	1.408	0.107	0.5	0.217
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
151	2.76	57	0.87	5.80	2.64	102	4.40
152	2.69	55	0.80	6.67	2.62	103	4.35
153	2.51	57	0.43	6.57	2.57	102	3.98
154	3.10	56	0.58	6.13	2.65	104	4.49
155	2.62	58	0.44	6.04	2.54	103	4.29
161	2.64	55	0.83	5.43	2.65	102	4.10
162	2.38	55	0.35	7.41	2.48	104	4.10
163	2.43	56	0.52	7.60	2.38	104	4.35
164	2.50	57	0.37	7.82	2.47	103	4.83
165	2.59	55	0.46	7.13	2.67	102	4.26
Mean	2.622	56.1	0.565	6.660	2.567	102.9	4.315
SD	0.204	1.1	0.197	0.812	0.097	0.9	0.239
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
181	2.74	57	0.51	7.50	2.44	103	4.09
182	2.09	59	0.35	7.64	2.69	103	4.56
183	2.30	58	0.52	6.12	2.87	100	4.02
184	2.77	53	0.34	6.80	2.57	103	3.54
185	2.66	56	0.36	5.24	2.66	104	4.35
191	2.45	53	0.41	5.55	2.54	103	3.96
192	2.60	53	0.57	6.11	2.55	104	4.11
193	2.60	55	0.54	7.61	2.52	104	3.75
194	2.72	59	0.88	11.36	2.65	103	3.97
195	2.76	56	0.59	9.05	2.83	103	4.08
Mean	2.569	55.9	0.507	7.298	2.632	103.0	4.043
SD	0.225	2.4	0.162	1.831	0.137	1.2	0.283
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
151	2.49	56	0.59	8.13	2.57	98	4.03
152	2.51	58	0.35	7.04	2.71	102	3.79
153	2.73	58	0.29	7.24	2.63	100	3.89
154	2.90	55	0.56	7.83	2.52	99	3.90
155	2.55	56	0.46	7.65	2.48	99	4.25
156	2.69	58	0.46	8.37	2.71	98	3.64
157	2.60	55	0.46	9.01	2.52	97	4.12
158	2.41	54	0.30	8.13	2.47	99	4.01
159	2.47	52	0.47	8.08	2.56	98	3.85
160	2.36	52	0.62	8.58	2.58	100	4.39
Mean	2.571	55.4	0.456	8.006	2.575	99.0	3.987
SD	0.163	2.3	0.115	0.595	0.086	1.4	0.223
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
1	1.99	55	0.26	7.30	2.57	101	4.51
2	1.81	53	0.26	7.79	2.45	104	4.04
3	1.90	57	0.46	7.48	2.57	101	3.91
4	2.60	54	0.63	6.14	2.71	101	4.38
5	2.68	55	0.60	6.68	2.59	100	3.29
6	2.42	54	0.49	6.27	2.48	99	3.55
7	2.28	55	0.42	8.16	2.64	101	3.88
8	2.21	50	0.45	7.36	2.43	100	3.52
9	2.45	50	0.30	5.96	2.54	100	4.20
10	2.11	54	0.26	6.54	2.48	99	3.76
Mean	2.245	53.7	0.413	6.968	2.546	100.6	3.904
SD	0.295	2.2	0.139	0.751	0.088	1.4	0.390
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
31	2.80	55	0.43	7.86	2.60	100	4.13
32	3.16	56	0.46	7.46	2.66	102	5.19
33	2.81	56	0.64	8.47	2.83	102	4.27
34	2.03	54	0.52	7.81	2.69	102	4.17
35	2.22	53	0.69	7.96	2.57	99	4.34
36	2.50	57	0.38	8.77	2.59	99	3.86
37	2.80	55	0.28	7.67	2.64	102	4.07
38	2.87	52	0.34	8.18	2.57	100	3.85
39	2.66	55	0.56	10.70	2.52	101	3.99
40	2.73	53	0.79	8.98	2.54	97	3.95
Mean	2.658	54.6	0.509	8.386	2.621	100.4	4.182
SD	0.329	1.6	0.163	0.947	0.090	1.7	0.390
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
61	2.72	54	0.56	7.19	2.48	99	3.94
62	2.58	56	0.65	8.31	2.47	99	3.81
63	2.48	51	0.44	8.25	2.40	99	3.84
64	1.99	56	0.61	7.94	2.59	102	4.13
65	2.15	54	0.52	8.34	2.48	98	3.89
66	2.42	55	0.46	8.27	2.45	99	3.83
67	2.39	50	0.56	8.03	2.56	100	4.14
68	2.38	55	0.59	6.88	2.59	100	3.87
69	2.59	54	0.57	8.37	2.62	101	4.02
70	2.46	52	0.44	11.09	2.48	101	4.12
Mean	2.416	53.7	0.540	8.267	2.512	99.8	3.959
SD	0.213	2.1	0.073	1.117	0.073	1.2	0.132
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
91	1.85	55	0.58	6.80	2.52	103	4.57
92	1.72	54	0.26	7.31	2.40	102	3.80
93	2.20	56	0.27	5.27	2.45	101	3.78
94	2.27	61	0.37	6.84	2.62	101	3.59
95	2.24	56	0.35	7.81	2.50	101	3.92
96	2.03	57	0.32	9.85	2.56	101	4.59
97	1.97	58	0.35	5.16	2.56	99	4.25
98	2.60	59	0.32	9.22	2.56	97	3.42
99	2.44	58	0.45	7.13	2.74	101	5.10
100	2.13	59	0.41	9.18	2.65	100	4.39
Mean	2.145	57.3	0.368	7.457	2.556	100.6	4.141
SD	0.265	2.1	0.094	1.596	0.098	1.6	0.527
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
121	2.77	59	0.54	9.33	2.52	99	3.43
122	2.61	57	0.32	6.61	2.56	101	4.11
123	2.31	58	0.71	7.32	2.53	99	4.05
124	2.45	60	0.53	8.56	2.65	103	4.76
125	2.34	56	0.41	10.04	2.47	99	3.96
126	2.38	59	0.60	10.19	2.59	103	4.36
127	1.95	59	0.51	8.71	2.65	100	4.19
128	1.87	60	0.46	8.18	2.64	100	4.19
129	2.24	63	0.48	8.22	2.65	100	3.61
130	4.16 E!	62	0.89	8.20	2.53	100	12.67 E!
Mean	2.324	59.3	0.545	8.536	2.579	100.4	4.073
SD	0.286	2.1	0.160	1.115	0.066	1.5	0.391
N	9	10	10	10	10	10	9

E = Exclude; ! = Result Comment

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
181	2.67	57	0.48	8.88	2.54	100	4.12
182	2.76	57	0.48	12.30	2.61	101	3.73
183	2.18	61	0.72	10.96	2.76	100	4.32
184	2.49	57	0.40	8.77	2.52	100	3.99
185	2.32	57	0.55	9.42	2.58	99	4.14
186	2.19	60	0.29	9.48	2.67	100	4.38
187	2.24	58	0.40	8.64	2.60	101	4.10
188	2.00	59	0.44	8.88	2.58	101	5.04
189	2.57	57	0.40	8.33	2.61	99	4.09
190	2.23	56	0.62	8.71	2.60	100	4.29
Mean	2.365	57.9	0.478	9.437	2.607	100.1	4.220
SD	0.245	1.6	0.124	1.246	0.068	0.7	0.342
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
161	1.90	57	0.45	6.41	2.50	104	3.65
162	1.87	55	0.45	6.86	2.33	103	3.89
163	1.87	54	0.75	5.91	2.34	104	3.80
164	3.14	57	0.30	6.88	2.50	105	5.93
165	1.82	56	0.38	6.47	2.40	103	3.94
Mean	2.120	55.8	0.466	6.506	2.414	103.8	4.242
SD	0.571	1.3	0.170	0.397	0.083	0.8	0.950
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
11	2.17	57	0.49	8.14	2.67	104	4.07
12	2.32	55	0.46	5.27	2.42	103	3.62
13	1.98	57	0.61	8.06	2.60	104	4.17
14	1.99	57	0.52	5.70	2.60	103	4.00
15	2.23	55	0.41	6.68	2.44	102	3.75
Mean	2.138	56.2	0.498	6.770	2.546	103.2	3.922
SD	0.150	1.1	0.075	1.318	0.110	0.8	0.229
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
41	2.36	58	0.41	6.65	2.60	103	3.96
42	2.10	55	0.28	6.91	2.57	101	4.08
43	2.00	54	0.44	6.92	2.43	102	4.19
44	2.50	56	0.72	8.14	2.62	101	4.07
45	2.00	54	0.53	7.29	2.48	103	4.04
Mean	2.192	55.4	0.476	7.182	2.540	102.0	4.068
SD	0.227	1.7	0.163	0.582	0.082	1.0	0.083
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
71	2.52	54	0.29	7.88	2.48	102	3.72
72	2.17	53	0.42	6.20	2.55	102	3.33
73	2.13	53	0.32	7.15	2.40	102	4.10
74	2.02	52	0.42	7.91	2.51	103	4.21
75	1.74	55	0.69	8.59	2.47	105	4.36
Mean	2.116	53.4	0.428	7.546	2.482	102.8	3.944
SD	0.281	1.1	0.158	0.909	0.055	1.3	0.417
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
101	2.03	56	0.55	9.19	2.45	103	3.98
102	1.92	59	0.62	6.76	2.40	104	3.84
103	2.34	57	0.51	7.67	2.42	102	3.95
104	2.30	60	0.66	6.60	2.58	102	3.61
105	1.91	53	0.50	7.96	2.47	105	4.08
Mean	2.100	57.0	0.568	7.636	2.464	103.2	3.892
SD	0.207	2.7	0.070	1.044	0.070	1.3	0.179
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
131	2.05	56	0.68	7.55	2.56	103	4.29
132	1.96	52	0.81	6.73	2.54	104	3.94
133	2.65	51	0.42	9.15	2.46	102	3.98
134	2.18	57	0.39	6.25	2.54	102	4.05
135	1.96	51	0.39	8.77	2.41	104	4.05
Mean	2.160	53.4	0.538	7.690	2.502	103.0	4.062
SD	0.288	2.9	0.195	1.256	0.064	1.0	0.136
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
191	2.26	59	0.60	7.63	2.59	103	4.22
192	2.31	57	0.89	7.71	2.55	104	4.09
193	2.01	57	0.59	9.47	2.53	105	4.16
194	2.16	56	0.55	7.29	2.47	105	3.82
195	2.23	55	0.93	5.37	2.47	103	3.92
Mean	2.194	56.8	0.712	7.494	2.522	104.0	4.042
SD	0.116	1.5	0.182	1.460	0.052	1.0	0.167
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
1	136	65	249	70	98	134	1.0
2	136	65	249	86	78	158	1.5
3	135	61	277	76	56	94	2.4
4	134	56	391	76	106	125	2.4
5	135	111	222	115	111	173	0.3
11	135	57	294	67	66	115	0.1
12	135	73	249	82	112	152	0.1 !
13	136	59	208	78	87	97	0.4
14	136	59	246	79	98	115	0.6
15	134	55	317	74	88	109	0.7
Mean	135.2	66.1	270.2	80.3	90.0	127.2	0.95
SD	0.8	16.7	53.3	13.4	18.9	26.6	0.87
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
31	136	55	222	87	54	150	4.0
32	136	55	227	84	47	95	4.5
33	136	68	239	81	90	126	4.5
34	136	69	292	88	82	207	4.9
35	135	64	246	93	78	170	5.6
41	135	51	255	84	58	198	4.5
42	134	54	273	83	57	137	5.1
43	134	56	329	80	102	210	3.0
44	135	52	260	83	51	123	2.6
45	137	45	236	88	67	351	3.4
Mean	135.4	56.9	257.9	85.1	68.6	176.7	4.21
SD	1.0	7.7	32.8	3.9	18.5	72.5	0.96
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
61	136	48	131	90	113	113	2.9
62	138	42	161	94	112	273	2.6
63	137	41	128	93	96	20	3.3
64	136	47	247	97	111	215	2.6
65	136	51	181	112	170	47	1.8
71	137	57	283	106	143	106	3.6
72	136	62	204	110	133	229	3.2
73	136	39	150	107	120	33	3.3
74	136	50	180	97	87	20	2.9
75	138	51	153	89	90	144	3.1
Mean	136.6	48.8	181.8	99.5	117.5	120.0	2.93
SD	0.8	7.1	50.3	8.5	25.6	93.1	0.51
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
91	136	51	278	72	58	113	3.0
92	136	63	320	82	77	156	1.4
93	136	52	252	78	75	291	3.0
94	136	68	227	70	71	123	2.3
95	135	69	239	76	149	261	2.5
101	137	68	277	84	68	217	3.1
102	136	73	240	79	97	194	2.7
103	135	58	277	72	62	85	2.0
104	136	49	206	72	77	268	2.9
105	136	68	259	88	81	458	2.3
Mean	135.9	61.9	257.5	77.3	81.5	216.6	2.52
SD	0.6	8.7	32.2	6.0	26.0	110.3	0.54
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
121	138	57	214	86	122	108	3.9
122	137	35	153	67	74	95	4.4
123	138	44	173	86	80	26	2.9
124	138	61	203	94	100	127	2.4
125	137	41	241	94	192	10	3.5
131	136	44	180	87	128	224	2.4
132	137	48	213	95	152	347	3.9
133	137	39	221	82	88	106	3.2
134	137	39	180	80	135	145	3.3
135	138	48	172	99	194	139	3.3
Mean	137.3	45.6	195.0	87.0	126.5	132.7	3.32
SD	0.7	8.2	27.4	9.3	43.1	96.4	0.65
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
151	136	38	145	87	153	52	2.8
152	136	53	172	100	111	139	5.2
153	136	42	208	94	111	137	4.0
154	137	47	218	104	153	227	4.2
155	138	43	167	89	124	152	4.5
161	138	43	171	91	110	127	4.3
162	137	47	197	93	80	221	2.7
163	138	42	206	96	133	158	1.4
164	136	44	214	92	184	154	3.5
165	136	43	200	108	190	160	3.4
Mean	136.8	44.2	189.8	95.4	134.9	152.7	3.60
SD	0.9	4.0	24.3	6.7	35.0	48.9	1.09
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
181	136	47	172	82	172	161	2.3
182	138	45	213	93	85	83	1.3
183	136	67	225	96	80	14	2.9
184	138	44	211	99	156	151	2.8
185	138	31	163	93	172	198	2.9
191	138	37	224	103	168	151	4.5
192	137	45	248	112	185	247	3.0
193	138	45	225	102	97	192	3.6
194	137	39	188	83	128	174	4.9
195	137	44	230	96	144	180	4.3
Mean	137.3	44.4	209.9	95.9	138.7	155.1	3.25
SD	0.8	9.3	27.2	9.0	39.1	64.8	1.09
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
151	132	43	132	97	141	147	3.3
152	133	49	165	116	125	141	6.1
153	133	45	164	108	140	221	3.1
154	131	58	177	125	163	233	2.8
155	132	46	152	108	133	167	3.1
156	134	55	178	100	108	111	4.0
157	129	49	148	101	131	128	4.2
158	131	51	160	113	112	208	5.6
159	133	47	169	110	67	92	3.2
160	133	52	158	126	126	78	4.4
Mean	132.1	49.5	160.3	110.4	124.6	152.6	3.98
SD	1.4	4.6	13.9	9.9	25.5	53.9	1.12
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
1	134	39	149	82	172	98	1.5
2	136	40	158	84	130	341	0.7
3	135	31	155	60	49	116	2.5
4	136	32	223	84	102	372	2.0
5	135	50	140	110	70	104	2.9
6	133	38	135	70	44	127	0.5
7	135	30	135	74	113	89	1.0
8	135	27	151	67	87	70	1.9
9	134	26	157	68	132	129	1.6
10	134	46	169	100	196	134	1.6
Mean	134.7	35.9	157.2	79.9	109.5	158.0	1.62
SD	0.9	8.0	25.5	15.6	49.9	106.7	0.76
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
31	134	44	201	113	95	154	4.2
32	135	29	166	91	196	193	3.8
33	136	54	169	116	147	311	4.4
34	136	41	232	106	119	120	3.2
35	133	34	157	97	175	118	5.6
36	132	44	181	95	117	165	4.7
37	136	32	204	82	65	120	4.4
38	132	48	155	115	143	168	4.5
39	134	31	232	85	121	159	5.4
40	130	44	209	113	162	148	4.1
Mean	133.8	40.1	190.6	101.3	134.0	165.6	4.43
SD	2.0	8.2	29.1	12.9	38.8	56.6	0.70
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
61	132	52	124	114	167	168	2.6
62	133	37	114	73	55	142	3.8
63	132	45	121	114	141	124	2.5
64	135	40	191	104	172	120	3.1
65	132	38	128	100	154	139	1.5
66	133	32	103	76	102	106	3.7
67	134	38	139	102	121	95	2.1
68	132	37	133	64	45	94	3.7
69	134	42	173	98	134	122	4.5
70	134	28	105	93	150	137	2.9
Mean	133.1	38.9	133.1	93.8	124.1	124.7	3.04
SD	1.1	6.6	28.5	17.3	44.2	22.9	0.90
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
91	133	36	153	98	133	111	4.1
92	136	37	177	101	92	126	4.2
93	133	38	134	89	80	229	2.9
94	135	34	127	77	58	136	3.1
95	136	29	133	78	81	192	3.7
96	134	37	142	93	146	179	4.5
97	133	40	123	89	102	178	3.0
98	132	36	114	88	82	137	3.8
99	137	40	123	94	128	139	3.5
100	135	35	178	80	132	115	3.1
Mean	134.4	36.2	140.4	88.7	103.4	154.2	3.59
SD	1.6	3.2	22.3	8.2	29.5	38.4	0.56
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
121	132	37	159	96	141	158	4.0
122	133	27	156	78	106	123	5.4
123	132	31	132	70	102	102	4.0
124	136	39	162	84	146	118	3.3
125	132	36	217	87	77	187	4.2
126	134	43	201	99	115	143	6.0
127	133	31	161	82	155	120	4.0
128	133	34	154	88	115	130	4.9
129	133	27	150	85	119	134	3.2
130	126	74	151	308 E!	2274 E!	245	2.8
Mean	132.4	37.9	164.3	85.4	119.6	146.0	4.18
SD	2.5	13.7	25.3	8.7	24.4	42.1	1.00
N	10	10	10	9	9	10	10

E = Exclude; ! = Result Comment

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
181	132	28	127	73	126	128	4.9
182	133	35	170	94	86	162	4.9
183	133	32	152	77	109	101	5.4
184	132	34	176	106	133	129	5.4
185	133	28	144	83	126	121	4.7
186	132	39	201	91	117	125	4.4
187	133	26	182	85	133	115	4.1
188	133	37	194	96	164	126	3.6
189	133	35	229	93	116	141	4.4
190	133	46	246	93	133	116	6.5
Mean	132.7	34.0	182.1	89.1	124.3	126.4	4.83
SD	0.5	6.0	37.1	9.7	20.1	16.3	0.81
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
161	138	49	117	110	122	226	2.3
162	138	48	119	84	138	115	2.0
163	139	42	144	85	99	78	2.2
164	140	47	143	72	150	197	1.5
165	137	34	126	80	93	101	1.2
Mean	138.4	44.0	129.8	86.2	120.4	143.4	1.84
SD	1.1	6.2	12.9	14.3	24.5	64.4	0.47
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
11	137	35	134	71	107	76	2.8
12	137	38	100	116	215	1117	1.6
13	135	32	100	69	106	114	3.6
14	137	31	94	76	78	133	1.7
15	137	37	126	70	61	85	3.3
Mean	136.6	34.6	110.8	80.4	113.4	305.0	2.60
SD	0.9	3.0	17.9	20.1	60.0	454.5	0.91
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
41	137	36	120	77	72	98	2.5
42	136	29	106	75	57	201	3.2
43	134	39	124	80	69	180	2.7
44	135	36	120	84	141	506	3.5
45	136	37	119	75	144	119	1.8
Mean	135.6	35.4	117.8	78.2	96.6	220.8	2.74
SD	1.1	3.8	6.9	3.8	42.3	165.0	0.66
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
71	138	37	145	86	140	82	1.8
72	138	42	116	83	52	67	2.0
73	137	36	84	109	209	354	1.9
74	138	33	90	75	101	92	2.6
75	140	37	103	80	161	273	1.1
Mean	138.2	37.0	107.6	86.6	132.6	173.6	1.88
SD	1.1	3.2	24.3	13.2	59.6	131.2	0.54
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
101	137	40	156	95	151	103	2.3
102	140	45	115	92	50	84	1.6
103	135	39	138	81	51	92	2.2
104	137	37	94	87	68	267	2.4
105	140	41	162	83	42	82	3.0
Mean	137.8	40.4	133.0	87.6	72.4	125.6	2.30
SD	2.2	3.0	28.5	5.9	44.9	79.5	0.50
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
131	138	44	143	102	179	282	0.6
132	139	40	112	87	68	338	0.3
133	137	35	157	74	52	199	1.9
134	136	37	114	76	127	252	1.6
135	139	44	106	105	102	107	2.3
Mean	137.8	40.0	126.4	88.8	105.6	235.6	1.34
SD	1.3	4.1	22.3	14.3	50.4	87.7	0.86
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
191	137	46	108	79	71	285	0.5
192	138	46	155	102	69	99	3.2
193	139	41	100	79	75	67	1.6
194	139	33	120	77	77	434	1.8
195	139	33	104	76	79	114	2.0
Mean	138.4	39.8	117.4	82.6	74.2	199.8	1.82
SD	0.9	6.5	22.3	10.9	4.1	155.9	0.97
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
16	29.6	24.4	1.21	3.5	1.76	42	11.14
17	29.7	28.3	1.05	4.7	1.53	42	7.86
18	32.3	28.7	1.13	4.6	1.67	45	8.72
19	31.0	27.0	1.15	3.3	2.20	44	9.52
20	32.3	25.7	1.26	3.2	2.07	44	8.60
26	33.7	28.3	1.19	4.1	2.26	43	8.87
27	31.5	28.5	1.11	2.4	1.47	38	9.94
28	30.3	26.7	1.13	3.1	1.64	46	8.47
29	32.2	29.8	1.08	3.5	2.28	45	8.39
30	33.5	29.5	1.14	2.7	1.77	45	8.86
Mean	31.61	27.69	1.144	3.51	1.865	43.4	9.037
SD	1.45	1.71	0.062	0.76	0.309	2.3	0.940
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
46	27.6	28.4	0.97	3.7	2.15	44	7.90
47	27.6	31.4	0.88	3.1	2.40	40	9.43
48	26.4	28.6	0.92	4.4	2.15	41	8.33
49	26.4	27.6	0.96	3.1	1.64	41	8.78
50	28.6	29.4	0.97	3.5	1.97	44	8.16
56	26.5	28.5	0.93	3.5	1.36	40	8.70
57	28.0	30.0	0.93	5.2	1.96	43	9.78
58	27.4	28.6	0.96	3.3	2.64	45	10.20
59	28.0	29.0	0.97	3.7	1.56	43	8.73
60	25.0	28.0	0.89	3.3	2.06	40	9.34
Mean	27.15	28.95	0.938	3.68	1.989	42.1	8.935
SD	1.06	1.09	0.033	0.65	0.388	1.9	0.737
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
76	28.3	26.7	1.06	2.9	2.10	50	6.29
77	26.9	23.1	1.16	2.3	1.86	45	9.88
78	27.7	28.3	0.98	3.4	2.70	39	5.46
79	27.0	23.0	1.17	2.8	1.73	45	6.75
80	30.1	27.9	1.08	2.6	2.12	45	6.18
86	27.4	25.6	1.07	2.4	1.77	45	6.56
87	27.5	24.5	1.12	2.4	2.14	40	5.73
88	28.0	26.0	1.08	2.8	2.16	43	8.70
89	29.3	26.7	1.10	3.1	2.10	47	6.69
90	28.1	24.9	1.13	3.2	1.94	45	6.65
Mean	28.03	25.67	1.095	2.79	2.062	44.4	6.889
SD	1.01	1.82	0.057	0.37	0.275	3.2	1.362
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
106	27.4	28.6	0.96	2.6	1.82	44	9.82
107	29.9	29.1	1.03	2.5	2.01	43	9.44
108	28.6	32.4	0.88	2.6	1.75	42	7.82
109	29.6	30.4	0.97	2.7	2.25	43	8.63
110	29.5	33.5	0.88	3.6	1.96	41	7.57
116	28.1	28.9	0.97	2.2	1.92	44	9.52
117	27.8	31.2	0.89	2.4	2.39	42	9.36
118	29.6	29.4	1.01	2.6	1.76	42	8.89
119	30.0	29.0	1.03	2.2	1.90	43	8.73
120	29.2	30.8	0.95	2.3	1.55	42	8.63
Mean	28.97	30.33	0.958	2.57	1.931	42.6	8.841
SD	0.93	1.65	0.057	0.40	0.245	1.0	0.731
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
136	28.7	29.3	0.98	2.3	2.38	42	9.69
137	27.7	27.3	1.01	2.3	1.51	44	9.99
138	27.3	26.7	1.02	2.7	1.68	47	6.58
139	29.1	29.9	0.97	3.2	1.27	48	7.08
140	28.4	34.6	0.82	3.2	1.99	43	6.23
146	27.2	28.8	0.94	3.2	1.40	42	9.05
147	29.1	32.9	0.88	2.9	2.70	41	6.09
148	28.2	28.8	0.98	2.7	2.06	36	4.97
149	27.8	27.2	1.02	2.3	1.86	43	6.67
150	28.6	33.4	0.86	2.9	1.80	45	6.32
Mean	28.21	29.89	0.950	2.77	1.865	43.1	7.267
SD	0.69	2.80	0.072	0.37	0.441	3.3	1.698
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
166	27.7	26.3	1.05	3.3	2.14	47	6.65
167	28.2	27.8	1.01	2.8	1.83	45	7.05
168	28.8	28.2	1.02	3.0	1.86	41	5.92
169	26.9	26.1	1.03	2.9	1.87	42	8.28
170	28.2	26.8	1.05	3.3	1.97	47	5.50
176	28.7	29.3	0.98	3.2	2.13	45	9.08
177	27.7	26.3	1.05	3.4	1.52	44	9.52
178	27.4	30.6	0.90	2.3	2.40	43	9.36
179	28.5	28.5	1.00	3.4	2.39	42	5.72
180	27.1	22.9	1.18	3.1	1.37	46	6.54
Mean	27.92	27.28	1.028	3.07	1.948	44.2	7.362
SD	0.66	2.12	0.072	0.34	0.336	2.1	1.562
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
196	28.0	29.0	0.97	3.4	1.58	48	6.35
197	27.2	28.8	0.94	2.5	2.03	42	5.10
198	26.5	27.5	0.96	2.4	1.79	42	6.21
199	27.5	27.5	1.00	3.3	2.14	40	8.81
200	27.4	27.6	0.99	2.4	1.63	41	5.94
206	28.2	28.8	0.98	2.7	1.84	46	5.70
207	27.9	28.1	0.99	2.5	1.75	40	7.25
208	29.4	32.6	0.90	2.4	2.23	45	7.47
209	28.2	29.8	0.95	2.6	1.65	40	6.05
210	25.9	27.1	0.96	3.1	1.89	44	6.33
Mean	27.62	28.68	0.964	2.73	1.853	42.8	6.521
SD	0.97	1.62	0.029	0.39	0.220	2.8	1.059
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
166	27.6	26.4	1.05	3.0	2.06	47	8.21
167	28.5	28.5	1.00	2.9	1.76	43	7.73
168	27.8	26.2	1.06	3.3	1.66	42	7.70
169	27.3	26.7	1.02	2.8	1.75	49	9.08
170	27.5	24.5	1.12	3.1	1.36	45	7.07
171	26.3	23.7	1.11	2.9	1.16	49	7.81
172	27.6	28.4	0.97	3.4	1.69	49	8.27
173	27.5	27.5	1.00	3.1	1.49	42	7.90
174	26.8	24.2	1.11	3.0	1.68	51	8.83
175	26.6	25.4	1.05	2.8	1.71	48	7.84
Mean	27.35	26.15	1.049	3.03	1.632	46.5	8.044
SD	0.64	1.70	0.052	0.20	0.246	3.3	0.582
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
16	29.7	23.3	1.27	2.2	1.66	52	9.51
17	29.3	28.7	1.02	2.6	1.15	46	8.50
18	31.5	26.5	1.19	3.1	1.56	42	10.23
19	28.4	24.6	1.15	3.4	2.40	47	8.43
20	31.6	26.4	1.20	3.6	2.01	51	9.21
21	30.9	26.1	1.18	3.1	1.90	46	10.47
22	29.7	24.3	1.22	2.7	1.42	41	9.56
23	30.9	25.1	1.23	4.0	2.18	48	9.70
24	31.7	26.3	1.21	2.9	1.95	49	8.62
25	29.9	24.1	1.24	2.7	1.41	46	10.79
Mean	30.36	25.54	1.192	3.03	1.764	46.8	9.502
SD	1.12	1.57	0.069	0.53	0.389	3.5	0.829
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
46	26.9	28.1	0.96	3.4	2.03	48	9.10
47	27.7	28.3	0.98	3.5	2.03	53	7.86
48	27.1	30.9	0.88	3.5	2.11	50	8.70
49	26.3	24.7	1.06	4.3	1.44	48	6.03
50	28.6	29.4	0.97	4.0	1.83	48	7.59
51	28.5	36.5	0.78	3.9	2.35	46	8.31
52	27.0	26.0	1.04	4.4	1.13	43	6.89
53	28.9	30.1	0.96	5.0	1.68	49	7.84
54	27.9	29.1	0.96	4.7	1.80	47	7.77
55	27.9	27.1	1.03	3.7	1.78	47	8.11
Mean	27.68	29.02	0.962	4.04	1.818	47.9	7.820
SD	0.84	3.23	0.083	0.55	0.349	2.6	0.873
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
76	27.4	27.6	0.99	2.8	2.38	48	10.88
77	27.7	26.3	1.05	3.5	2.23	46	8.83
78	26.9	26.1	1.03	3.5	2.41	49	7.62
79	27.4	25.6	1.07	3.5	1.91	48	8.65
80	26.9	25.1	1.07	3.6	1.79	46	8.04
81	28.0	23.0	1.22	3.3	1.27	52	7.92
82	29.2	24.8	1.18	4.0	1.53	52	7.40
83	28.4	26.6	1.07	3.9	1.77	50	7.70
84	27.8	28.2	0.99	3.3	2.10	48	8.58
85	27.2	24.8	1.10	4.7	1.55	53	9.71
Mean	27.69	25.81	1.076	3.61	1.894	49.2	8.533
SD	0.71	1.50	0.073	0.51	0.384	2.5	1.076
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
106	26.0	28.0	0.93	3.4	1.60	47	11.67
107	27.5	27.5	1.00	2.9	1.48	49	6.88
108	28.2	31.8	0.89	4.5	1.21	43	8.25
109	27.0	29.0	0.93	2.5	1.89	49	7.68
110	29.7	33.3	0.89	2.8	1.60	46	8.48
111	27.4	30.6	0.90	3.2	1.70	48	9.29
112	26.7	30.3	0.88	2.6	1.16	47	9.94
113	26.4	29.6	0.89	2.8	1.64	48	8.72
114	27.1	30.9	0.88	2.9	1.09	48	6.19
115	27.8	30.2	0.92	3.0	1.11	47	9.04
Mean	27.38	30.12	0.910	3.06	1.448	47.2	8.614
SD	1.04	1.72	0.037	0.57	0.284	1.8	1.551
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
136	26.4	28.6	0.92	3.8	1.53	48	8.12
137	27.9	30.1	0.93	3.9	1.73	47	7.51
138	25.9	24.1	1.07	2.9	1.32	49	9.96
139	28.0	30.0	0.93	4.0	1.01	49	7.43
140	27.2	29.8	0.91	5.0	1.28	49	7.78
141	29.5	33.5	0.88	4.5	2.07	54	8.03
142	26.6	29.4	0.90	3.4	1.54	47	9.39
143	26.9	28.1	0.96	3.6	1.65	48	6.65
144	26.9	30.1	0.89	2.7	1.15	54	9.29
145	26.4	28.6	0.92	4.5	1.16	48	7.51
Mean	27.17	29.23	0.933	3.83	1.444	49.3	8.167
SD	1.05	2.34	0.054	0.72	0.322	2.6	1.046
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
196	27.1	28.9	0.94	5.1	1.25	50	7.78
197	26.4	28.6	0.92	5.5	1.53	46	9.07
198	27.6	32.4	0.85	2.5	1.17	53	11.01
199	26.9	30.1	0.89	3.1	1.25	46	9.37
200	28.2	29.8	0.95	3.8	1.45	51	7.30
201	27.3	28.7	0.95	3.4	1.14	53	8.94
202	27.1	31.9	0.85	5.1	1.25	51	7.70
203	26.9	29.1	0.92	3.7	1.52	47	9.22
204	25.6	28.4	0.90	3.5	1.09	55	7.24
205	27.2	32.8	0.83	3.9	1.40	50	7.24
Mean	27.03	30.07	0.901	3.96	1.305	50.2	8.487
SD	0.69	1.68	0.044	0.97	0.159	3.1	1.241
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
176	31.2	28.8	1.08	3.7	1.57	58	10.02
177	29.9	28.1	1.06	3.5	1.07	54	8.85
178	33.7	30.3	1.11	4.0	2.39	48	10.44
179	30.2	28.8	1.05	2.5	1.80	49	9.89
180	30.5	26.5	1.15	3.6	1.37	55	8.33
Mean	31.10	28.50	1.092	3.46	1.640	52.8	9.506
SD	1.53	1.38	0.041	0.57	0.498	4.2	0.880
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
26	32.9	29.1	1.13	3.1	2.42	53	11.08
27	30.1	29.9	1.01	2.7	1.34	54	9.10
28	28.0	29.0	0.97	2.8	1.52	53	9.60
29	31.7	30.3	1.05	2.6	2.21	56	7.47
30	33.6	29.4	1.14	2.7	1.90	60	8.43
Mean	31.26	29.54	1.058	2.78	1.878	55.2	9.136
SD	2.25	0.55	0.077	0.19	0.453	2.9	1.348
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
56	30.1	28.9	1.04	2.8	1.30	51	9.36
57	34.2	31.8	1.08	5.2	2.14	51	8.79
58	29.7	29.3	1.01	2.6	2.87	52	10.33
59	31.1	32.9	0.95	2.8	1.39	59	6.61
60	29.7	30.3	0.98	3.5	2.06	49	9.02
Mean	30.96	30.64	1.011	3.38	1.952	52.4	8.822
SD	1.90	1.69	0.051	1.07	0.638	3.8	1.369
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
86	29.9	25.1	1.19	3.6	1.32	54	8.70
87	29.2	24.8	1.18	3.4	1.59	50	7.81
88	29.8	22.2	1.34	3.0	2.00	50	9.94
89	29.3	22.7	1.29	2.9	1.27	51	10.15
90	30.6	24.4	1.25	3.4	1.95	50	11.49
Mean	29.76	23.84	1.251	3.26	1.626	51.0	9.618
SD	0.56	1.30	0.069	0.30	0.342	1.7	1.414
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
116	30.3	31.7	0.96	2.5	1.78	60	9.80
117	30.3	28.7	1.06	2.9	1.80	54	10.38
118	32.1	30.9	1.04	3.4	1.58	52	11.70
119	30.3	27.7	1.09	2.8	1.92	51	7.72
120	31.0	31.0	1.00	3.4	1.82	57	10.97
Mean	30.80	30.00	1.029	3.00	1.780	54.8	10.114
SD	0.79	1.71	0.053	0.39	0.124	3.7	1.512
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
146	28.5	24.5	1.16	2.6	1.24	53	11.75
147	33.0	31.0	1.06	3.5	2.73	50	10.91
148	32.2	26.8	1.20	2.6	2.05	52	6.75
149	29.1	25.9	1.12	3.2	1.47	65	9.53
150	31.6	30.4	1.04	3.8	1.53	56	11.88
Mean	30.88	27.72	1.118	3.14	1.804	55.2	10.164
SD	1.97	2.85	0.067	0.54	0.596	5.9	2.126
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
206	31.2	28.8	1.08	2.8	2.05	47	8.13
207	30.2	27.8	1.09	3.3	1.96	55	12.40
208	31.4	23.6	1.33	3.0	2.50	52	9.87
209	30.7	27.3	1.12	2.8	2.08	50	6.96
210	29.0	28.0	1.04	2.4	1.60	52	9.31
Mean	30.50	27.10	1.132	2.86	2.038	51.2	9.334
SD	0.96	2.03	0.115	0.33	0.321	2.9	2.048
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
16	1.87	54	2.06	6.45	2.64	102	4.19
17	2.58	58	1.54	7.49	2.81	101	4.45
18	2.09	61	2.22	9.09	2.74	102	4.42
19	2.37	58	1.30	7.13	2.81	103	4.22
20	2.09	58	1.11	6.26	2.79	103	3.78
26	2.19	62	2.36	7.19	2.88	102	4.48
27	1.99	60	0.87	5.60	2.69	102	3.88
28	2.41	57	1.26	6.40	2.79	101	4.23
29	2.41	62	2.17	7.01	2.90	101	4.58
30	2.07	63	0.71	6.51	2.65	105	4.21
Mean	2.207	59.3	1.560	6.913	2.770	102.2	4.244
SD	0.225	2.8	0.602	0.943	0.089	1.2	0.257
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
46	2.52	56	2.19	7.54	2.83	101	4.10
47	2.23	59	1.22	7.27	2.93	103	4.38
48	2.28	55	2.41	6.98	2.90	100	4.36
49	2.54	54	1.54	6.16	2.78	101	3.84
50	2.56	58	1.62	7.03	2.80	100	3.90
56	2.53	55	1.90	6.41	2.71	100	4.05
57	2.46	58	2.89	6.53	2.84	100	4.22
58	2.38	56	1.49	5.70	2.77	102	3.93
59	2.47	57	1.22	7.98	2.81	100	4.14
60	2.90	53	1.98	8.06	2.78	100	4.26
Mean	2.487	56.1	1.846	6.966	2.815	100.7	4.118
SD	0.183	1.9	0.538	0.775	0.064	1.1	0.190
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
76	2.52	55	0.74	7.66	2.66	103	3.69
77	2.15	50	0.38	7.60	2.55	104	4.11
78	2.75	56	0.52	7.15	2.82	102	4.04
79	2.02	50	0.54	5.67	2.60	103	3.45
80	2.21	58	0.62	5.22	2.76	103	3.86
86	2.20	53	0.46	7.19	2.53	103	3.83
87	2.44	52	0.44	4.95	2.72	103	3.81
88	2.00	54	0.44	8.01	2.49	103	3.78
89	2.27	56	0.61	4.83	2.63	104	4.17
90	2.22	53	0.46	7.94	2.64	105	3.70
Mean	2.278	53.7	0.521	6.622	2.640	103.3	3.844
SD	0.231	2.6	0.109	1.299	0.104	0.8	0.216
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
106	2.18	56	1.33	5.99	2.80	101	4.68
107	2.37	59	0.83	5.61	2.86	100	3.74
108	2.40	61	0.68	7.85	2.81	102	4.68
109	2.27	60	1.21	7.35	2.86	103	4.22
110	2.19	63	1.32	7.08	2.89	102	4.05
116	2.46	57	0.67	6.21	2.64	103	4.20
117	2.28	59	0.67	6.93	2.77	102	4.15
118	2.46	59	1.26	8.03	2.94	101	4.37
119	2.24	59	0.50	7.42	2.76	102	3.85
120	2.44	60	0.59	7.17	2.85	101	4.32
Mean	2.329	59.3	0.906	6.964	2.818	101.7	4.226
SD	0.110	1.9	0.334	0.795	0.083	0.9	0.309
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
136	2.35	58	0.39	6.44	2.84	104	4.19
137	2.11	55	0.42	6.04	2.70	102	4.48
138	2.07	54	0.28	7.70	2.50	104	3.69
139	2.60	59	0.27	8.61	2.69	104	4.25
140	2.28	63	0.84	6.48	2.77	104	3.76
146	1.96	56	0.80	6.72	2.81	102	4.78
147	2.50	62	0.70	7.00	2.79	103	3.82
148	2.69	57	0.71	6.64	2.80	103	4.04
149	2.26	55	0.48	4.75	2.55	103	3.62
150	2.39	62	0.45	5.66	2.79	104	3.77
Mean	2.321	58.1	0.534	6.604	2.724	103.3	4.040
SD	0.234	3.3	0.211	1.059	0.115	0.8	0.381
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
166	2.49	54	0.66	8.02	2.61	103	4.00
167	2.71	56	0.57	6.86	2.67	104	4.02
168	2.38	57	0.32	4.38	2.66	104	3.68
169	2.74	53	0.53	6.20	2.70	102	4.07
170	2.81	55	0.62	7.51	2.70	102	3.95
176	2.23	58	0.77	6.16	2.71	102	4.02
177	2.11	54	0.82	6.74	2.72	102	4.37
178	2.63	58	1.26	6.72	2.89	101	4.31
179	2.52	57	0.54	7.71	2.81	102	3.78
180	2.74	50	0.69	9.05	2.62	103	3.86
Mean	2.536	55.2	0.678	6.935	2.709	102.5	4.006
SD	0.236	2.5	0.248	1.262	0.085	1.0	0.214
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
196	2.11	57	0.32	6.03	2.56	105	3.66
197	2.60	56	0.31	5.87	2.70	104	3.99
198	2.39	54	0.52	5.81	2.73	103	4.04
199	2.41	55	0.93	6.16	2.72	102	4.64
200	2.25	55	0.37	6.36	2.60	104	3.70
206	2.28	57	0.37	7.42	2.73	104	4.14
207	2.16	56	0.34	5.60	2.66	103	3.81
208	2.29	62	0.38	6.14	2.81	103	4.32
209	2.47	58	0.35	5.34	2.74	104	3.71
210	2.59	53	0.52	6.74	2.69	101	3.79
Mean	2.355	56.3	0.441	6.147	2.694	103.3	3.980
SD	0.167	2.5	0.187	0.594	0.072	1.2	0.316
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
166	1.90	54	0.51	9.09	2.54	102	4.04
167	2.17	57	0.43	7.95	2.64	101	4.19
168	2.17	54	0.47	7.89	2.75	99	4.45
169	2.11	54	0.56	8.00	2.46	102	3.64
170	2.28	52	0.33	8.73	2.68	101	4.07
171	2.36	50	0.35	7.77	2.53	100	3.99
172	2.34	56	0.54	9.82	2.53	96	4.12
173	2.25	55	0.63	8.56	2.64	100	3.81
174	2.53	51	0.37	9.29	2.56	100	3.55
175	2.25	52	0.34	8.82	2.64	101	4.33
Mean	2.236	53.5	0.453	8.592	2.597	100.2	4.019
SD	0.167	2.2	0.105	0.687	0.087	1.8	0.285
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
16	1.98	53	0.37	7.92	2.44	101	3.05
17	1.54	58	0.23	7.41	2.55	102	3.98
18	1.99	58	0.34	7.06	2.61	103	3.60
19	2.45	53	0.58	6.35	2.80	100	3.52
20	1.95	58	0.28	10.15	2.67	102	3.09
21	1.70	57	0.34	8.10	2.50	101	3.71
22	1.44	54	0.34	6.57	2.42	103	3.34
23	2.07	56	0.35	6.34	2.62	103	3.90
24	1.66	58	0.27	9.22	2.56	102	3.83
25	1.67	54	0.30	9.51	2.57	102	3.88
Mean	1.845	55.9	0.340	7.863	2.574	101.9	3.590
SD	0.300	2.2	0.095	1.373	0.111	1.0	0.336
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
46	2.28	55	0.78	7.97	2.67	101	3.89
47	2.16	56	0.51	7.52	2.66	100	4.00
48	2.28	58	0.42	6.84	2.66	102	3.77
49	2.37	51	0.60	7.30	2.53	99	3.55
50	2.07	58	0.42	7.97	2.62	98	3.48
51	2.09	65	0.51	6.67	2.81	101	4.18
52	2.39	53	0.31	6.51	2.66	102	3.87
53	2.58	59	0.39	10.55	2.73	101	3.86
54	2.48	57	0.36	7.42	2.81	100	4.30
55	1.76	55	0.45	9.75	2.51	104	4.09
Mean	2.246	56.7	0.475	7.850	2.666	100.8	3.899
SD	0.237	3.8	0.136	1.322	0.100	1.7	0.259
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
76	1.84	55	0.53	8.00	2.70	102	4.15
77	1.70	54	0.60	9.30	2.49	105	3.81
78	2.04	53	0.41	8.73	2.45	101	3.89
79	2.03	53	0.41	8.09	2.55	103	4.11
80	2.13	52	0.88	7.99	2.67	102	4.07
81	2.47	51	0.35	9.13	2.57	102	3.85
82	1.92	54	0.93	6.43	2.54	102	3.71
83	2.13	55	0.64	7.33	2.72	102	4.04
84	2.30	56	0.89	9.55	2.71	101	4.36
85	1.87	52	0.39	6.39	2.47	103	3.97
Mean	2.043	53.5	0.603	8.094	2.587	102.3	3.996
SD	0.228	1.6	0.225	1.122	0.104	1.2	0.190
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
106	2.29	54	0.30	7.18	2.56	102	4.34
107	2.01	55	0.42	6.79	2.64	101	3.77
108	2.17	60	0.32	8.29	2.80	100	4.21
109	2.66	56	0.48	7.54	2.74	102	3.84
110	1.84	63	0.35	8.12	2.76	102	3.67
111	2.27	58	0.33	8.58	2.72	101	3.99
112	1.90	57	0.27	9.67	2.59	102	4.11
113	2.12	56	0.44	7.98	2.71	100	3.74
114	2.26	58	0.37	9.06	2.49	102	3.64
115	1.72	58	0.29	7.84	2.62	101	3.71
Mean	2.124	57.5	0.357	8.105	2.663	101.3	3.902
SD	0.272	2.6	0.070	0.857	0.099	0.8	0.246
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
136	2.16	55	0.47	7.74	2.74	100	4.06
137	2.36	58	0.59	8.28	2.62	102	4.37
138	1.50	50	0.37	9.92	2.48	103	4.08
139	1.64	58	0.27	8.64	2.65	102	4.17
140	2.54	57	0.54	9.61	2.68	99	4.42
141	2.02	63	0.37	8.04	2.74	102	3.93
142	1.98	56	0.46	6.22	2.64	102	4.32
143	2.56	55	0.53	7.73	2.55	100	3.37
144	1.97	57	0.33	10.60	2.59	101	4.83
145	2.15	55	0.51	7.75	2.71	103	4.25
Mean	2.088	56.4	0.444	8.453	2.640	101.4	4.180
SD	0.347	3.3	0.104	1.284	0.084	1.3	0.378
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
196	2.17	56	0.51	8.72	2.71	103	4.10
197	2.27	55	0.41	8.10	2.71	101	4.37
198	1.86	60	0.47	9.84	2.83	104	4.38
199	1.94	57	0.26	7.38	2.61	101	3.46
200	1.82	58	0.29	6.71	2.63	103	3.39
201	2.30	56	0.54	9.53	2.74	101	3.92
202	2.19	59	0.39	8.16	2.75	102	4.27
203	2.12	56	0.57	7.77	2.64	101	4.00
204	2.01	54	0.52	9.98	2.65	104	3.80
205	1.71	60	0.54	7.05	2.58	104	3.85
Mean	2.039	57.1	0.450	8.324	2.685	102.4	3.954
SD	0.202	2.1	0.109	1.162	0.076	1.3	0.346
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
176	1.50	60	0.28	7.13	2.49	103	3.56
177	1.79	58	0.24	5.88	2.45	102	3.66
178	1.56	64	0.61	8.93	2.66	101	3.32
179	1.63	59	0.43	8.11	2.46	102	3.54
180	2.02	57	0.42	6.94	2.55	103	3.57
Mean	1.700	59.6	0.396	7.398	2.522	102.2	3.530
SD	0.209	2.7	0.146	1.166	0.086	0.8	0.126
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
26	1.33	62	0.55	9.27	2.57	101	3.64
27	1.78	60	0.34	7.40	2.59	105	3.04
28	1.81	57	0.36	7.54	2.46	102	3.98
29	1.58	62	0.30	7.99	2.66	103	3.36
30	1.65	63	0.49	7.85	2.64	105	3.50
Mean	1.630	60.8	0.408	8.010	2.584	103.2	3.504
SD	0.192	2.4	0.107	0.743	0.078	1.8	0.347
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
56	1.61	59	0.38	6.95	2.50	104	3.50
57	1.98	66	0.47	6.57	2.66	104	3.22
58	1.71	59	0.42	8.90	2.55	101	3.83
59	1.91	64	0.33	6.51	2.49	105	2.97
60	1.72	60	0.43	9.48	2.53	104	3.61
Mean	1.786	61.6	0.406	7.682	2.546	103.6	3.426
SD	0.153	3.2	0.053	1.402	0.068	1.5	0.336
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
86	2.10	55	0.37	9.10	2.43	102	3.83
87	1.85	54	0.32	8.49	2.44	103	3.79
88	1.76	52	0.49	8.54	2.48	101	3.86
89	1.56	52	0.44	7.58	2.46	102	3.56
90	1.88	55	0.47	8.12	2.57	104	3.71
Mean	1.830	53.6	0.418	8.366	2.476	102.4	3.750
SD	0.196	1.5	0.071	0.562	0.056	1.1	0.120
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
116	1.80	62	0.26	9.22	2.47	103	3.37
117	1.68	59	0.37	7.35	2.62	103	3.58
118	1.78	63	0.36	8.55	2.68	104	3.99
119	1.86	58	0.45	7.47	2.52	104	3.21
120	1.78	62	0.30	9.36	2.64	102	3.72
Mean	1.780	60.8	0.348	8.390	2.586	103.2	3.574
SD	0.065	2.2	0.073	0.946	0.088	0.8	0.304
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
146	1.57	53	0.25	7.69	2.47	102	3.82
147	1.33	64	0.79	6.26	2.56	104	3.51
148	1.58	59	0.38	5.98	2.47	102	2.99
149	2.27	55	0.42	7.81	2.30	103	3.59
150	2.13	62	0.58	8.41	2.65	102	3.70
Mean	1.776	58.6	0.484	7.230	2.490	102.6	3.522
SD	0.403	4.6	0.208	1.054	0.130	0.9	0.319
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
206	2.32	60	0.51	8.18	2.69	104	3.97
207	1.69	58	0.45	6.53	2.48	101	3.67
208	1.41	55	0.34	8.17	2.53	105	3.95
209	2.36	58	0.36	7.01	2.45	103	3.30
210	1.76	57	0.32	7.75	2.40	103	3.01
Mean	1.908	57.6	0.396	7.528	2.510	103.2	3.580
SD	0.416	1.8	0.081	0.733	0.111	1.5	0.418
N	5	5	5	5	5	5	5

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
16	136	59	138	86	76	207	0.1 !
17	135	61	172	83	99	129	0.8
18	136	61	148	85	122	88	1.9
19	135	51	136	51	66	51	1.5
20	137	59	132	71	87	164	0.8
26	135	50	149	65	82	136	1.2
27	136	46	169	41	59	85	0.2
28	135	65	214	75	99	94	0.7
29	135	70	139	79	73	129	0.3
30	138	51	145	109	98	97	1.3
Mean	135.8	57.3	154.2	74.5	86.1	118.0	0.88
SD	1.0	7.6	24.9	19.2	18.8	44.8	0.59
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
46	135	61	231	91	83	158	4.6
47	138	54	168	98	74	124	3.2
48	135	64	251	84	67	341	4.7
49	135	59	219	85	72	96	3.5
50	135	54	159	80	54	92	2.6
56	134	50	217	84	65	80	5.4
57	135	54	138	77	60	96	3.4
58	135	55	184	71	72	63	1.6
59	134	75	190	108	83	131	4.2
60	134	65	223	80	57	155	3.5
Mean	135.0	59.1	198.0	85.8	68.7	133.6	3.67
SD	1.2	7.4	35.9	10.7	10.0	79.3	1.10
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
76	136	55	192	107	99	19	3.3
77	137	37	129	109	122	236	2.6
78	136	57	152	93	73	139	3.4
79	136	49	142	93	105	86	2.7
80	137	39	145	106	142	243	2.8
86	136	44	124	107	109	360	2.4
87	139	41	143	85	63	88	3.1
88	136	41	120	84	97	106	3.2
89	138	31	135	96	231	241	2.4
90	137	61	135	108	162	16	1.6
Mean	136.8	45.5	141.7	98.8	120.3	153.4	2.75
SD	1.0	9.7	20.2	9.8	48.7	112.3	0.54
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
106	135	47	182	75	52	144	2.4
107	135	55	133	77	70	104	2.6
108	135	59	187	77	53	71	2.0
109	137	44	155	71	71	97	0.7
110	136	39	165	66	82	95	2.4
116	136	34	151	75	97	277	2.2
117	135	57	185	94	68	239	1.7
118	135	75	208	87	68	121	2.6
119	136	48	159	84	57	69	1.9
120	134	32	152	52	58	80	4.7
Mean	135.4	49.0	167.7	75.8	67.6	129.7	2.32
SD	0.8	13.0	22.3	11.6	13.9	71.8	1.01
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
136	138	49	138	97	88	120	4.1
137	135	41	140	98	114	13	1.3
138	138	30	132	96	201	163	2.3
139	136	40	130	95	195	9	4.0
140	137	40	214	89	98	127	5.8
146	136	51	140	87	161	487	3.7
147	136	33	141	72	79	26	3.5
148	138	49	175	108	113	29	4.9
149	136	37	154	87	105	99	2.1
150	137	31	142	78	96	117	5.5
Mean	136.7	40.1	150.6	90.7	125.0	119.0	3.72
SD	1.1	7.6	25.7	10.4	44.3	140.6	1.48
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
166	136	42	124	85	140	32	4.2
167	136	55	173	109	91	24	2.4
168	138	45	143	106	146	116	4.7
169	135	42	185	101	141	23	4.3
170	135	47	110	109	143	392	3.2
176	136	71	180	120	156	99	4.1
177	136	54	158	117	236	206	3.1
178	135	64	164	113	102	315	3.0
179	135	53	156	101	143	134	4.6
180	135	48	122	111	131	26	4.1
Mean	135.7	52.1	151.5	107.2	142.9	136.7	3.77
SD	0.9	9.5	25.9	9.9	38.5	130.2	0.78
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
196	138	23	154	78	138	140	3.6
197	137	32	166	103	138	157	4.5
198	137	38	118	89	131	140	3.2
199	135	44	182	90	139	48	4.5
200	138	42	125	90	78	87	4.3
206	136	34	160	109	104	136	3.7
207	139	29	155	78	67	98	3.4
208	135	42	186	110	236	6	5.9
209	138	32	177	100	118	233	3.0
210	135	48	190	119	184	16	4.0
Mean	136.8	36.4	161.3	96.6	133.3	106.1	4.01
SD	1.5	7.7	24.5	13.8	49.2	69.8	0.85
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
166	135	129	109	160	80	82	3.7
167	133	63	168	124	119	113	4.5
168	130	58	145	119	121	101	4.6
169	134	35	165	113	124	145	5.2
170	133	46	118	118	124	129	4.9
171	132	48	122	111	96	137	4.2
172	128	35	104	100	120	158	5.4
173	132	65	143	123	77	105	3.5
174	133	62	134	127	118	140	3.0
175	133	40	209	130	107	112	3.6
Mean	132.3	58.1	141.7	122.5	108.6	122.2	4.26
SD	2.0	27.4	32.1	15.8	18.1	23.4	0.79
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
16	135	31	72	83	46	64	0.6
17	135	31	92	83	181	133	0.9
18	135	30	71	72	110	98	0.3
19	134	26	72	60	106	158	1.2
20	134	42	73	96	179	154	1.8
21	134	36	64	85	148	98	1.4
22	135	49	73	87	146	87	1.2
23	136	27	60	70	103	97	1.1
24	136	36	86	90	103	92	2.4
25	135	34	96	80	131	85	1.2
Mean	134.9	34.2	75.9	80.6	125.3	106.6	1.21
SD	0.7	7.0	11.7	10.6	40.6	31.1	0.59
N	10	10	10	10	10	10	10

TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
46	134	31	154	89	106	104	5.0
47	132	120	113	156	152	216	3.0
48	134	47	177	109	102	127	4.3
49	132	43	138	109	168	183	3.9
50	131	44	142	95	126	112	4.7
51	133	67	163	122	190	135	3.8
52	134	37	178	109	124	113	3.4
53	134	55	184	124	129	109	4.7
54	133	81	174	152	220	536	4.0
55	134	53	136	122	100	122	2.9
Mean	133.1	57.8	155.9	118.7	141.7	175.7	3.97
SD	1.1	26.2	23.2	21.8	40.2	131.6	0.72
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
76	136	41	170	115	116	352	4.5
77	137	30	112	80	185	82	5.4
78	133	40	93	90	165	127	3.6
79	136	43	137	114	176	102	1.1
80	134	38	144	99	141	133	3.4
81	133	36	121	79	119	99	3.4
82	133	34	82	98	171	448	2.0
83	133	50	119	102	181	110	2.0
84	132	35	123	88	130	252	3.2
85	134	32	104	88	175	118	4.6
Mean	134.1	37.9	120.5	95.3	155.9	182.3	3.32
SD	1.7	5.9	25.5	12.6	26.7	125.9	1.33
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
106	133	36	114	103	143	347	2.3
107	134	42	77	102	119	115	3.0
108	133	44	142	99	133	78	4.5
109	135	27	86	74	140	363	4.0
110	131	26	110	63	46	67	2.9
111	134	33	128	88	127	204	6.0
112	135	31	149	91	123	100	4.2
113	134	40	93	84	56	121	3.2
114	133	28	89	76	49	97	4.4
115	132	36	99	84	110	158	4.9
Mean	133.4	34.3	108.7	86.4	104.6	165.0	3.94
SD	1.3	6.4	24.5	13.0	38.7	107.7	1.10
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
136	128	45	135	115	167	136	3.7
137	133	38	151	115	187	411	4.3
138	135	39	191	103	163	157	5.1
139	132	27	136	100	168	131	4.1
140	131	40	206	118	149	242	5.0
141	134	32	121	99	181	106	3.7
142	133	32	129	99	146	235	4.9
143	133	30	170	91	50	109	5.2
144	132	25	159	92	112	170	4.3
145	135	26	191	95	151	140	3.7
Mean	132.6	33.4	158.9	102.7	147.4	183.7	4.40
SD	2.1	6.8	29.6	9.9	40.1	92.6	0.61
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
196	134	26	204	101	174	166	5.6
197	133	45	198	134	266	114	4.5
198	136	35	144	91	200	142	5.0
199	132	32	195	96	131	149	5.0
200	135	29	168	91	90	171	3.0
201	131	19	205	94	85	110	4.9
202	132	33	161	104	202	189	5.2
203	133	32	223	98	122	116	5.3
204	137	29	172	97	197	151	5.6
205	135	28	168	96	87	88	6.4
Mean	133.8	30.8	183.8	100.2	155.4	139.6	5.05
SD	1.9	6.7	24.6	12.5	61.5	31.8	0.88
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
176	138	26	74	77	138	88	2.4
177	136	29	72	100	110	703	1.8
178	135	49	72	123	106	184	1.8
179	136	32	80	71	126	154	2.5
180	137	24	44	62	110	124	2.2
Mean	136.4	32.0	68.4	86.6	118.0	250.6	2.14
SD	1.1	10.0	14.0	24.7	13.6	255.4	0.33
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
26	135	35	54	82	62	93	3.0
27	140	28	63	74	53	84	1.2
28	134	29	83	72	135	171	2.8
29	137	41	59	77	56	168	2.4
30	138	44	48	91	41	85	3.0
Mean	136.8	35.4	61.4	79.2	69.4	120.2	2.48
SD	2.4	7.1	13.3	7.6	37.5	45.2	0.76
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
56	138	29	57	82	54	60	3.4
57	137	76	37	172	203	671	1.9
58	134	29	80	51	30	48	3.3
59	139	35	73	91	40	141	3.3
60	139	34	90	78	123	105	3.4
Mean	137.4	40.6	67.4	94.8	90.0	205.0	3.06
SD	2.1	20.0	20.8	45.7	72.9	263.1	0.65
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
86	135	35	85	83	141	151	2.1
87	136	29	72	81	176	166	2.8
88	135	32	71	61	74	85	0.5
89	137	28	69	73	122	206	1.4
90	137	38	65	99	150	969	1.9
Mean	136.0	32.4	72.4	79.4	132.6	315.4	1.74
SD	1.0	4.2	7.5	14.0	38.1	368.0	0.86
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
116	137	24	64	72	59	168	3.2
117	136	41	64	105	83	136	2.6
118	137	32	63	91	158	349	1.4
119	137	32	63	88	46	111	2.6
120	136	23	69	67	155	278	2.8
Mean	136.6	30.4	64.6	84.6	100.2	208.4	2.52
SD	0.5	7.3	2.5	15.3	53.1	101.2	0.67
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
146	137	38	67	72	108	194	2.2
147	137	30	56	61	53	51	1.6
148	137	34	62	87	50	79	3.2
149	136	37	88	114	193	324	1.8
150	138	38	51	93	138	179	1.8
Mean	137.0	35.4	64.8	85.4	108.4	165.4	2.12
SD	0.7	3.4	14.3	20.3	60.2	108.1	0.64
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
206	138	36	73	71	43	123	2.4
207	135	36	69	75	87	120	2.5
208	138	34	59	98	172	253	1.8
209	139	24	68	80	80	156	2.0
210	139	28	66	87	63	107	3.5
Mean	137.8	31.6	67.0	82.2	89.0	151.8	2.44
SD	1.6	5.4	5.1	10.7	49.4	59.4	0.66
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	5	Male	130	Phosphate	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			
	17	5	Male	130	Potassium	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	4	1	Male	12	Gamma-GT	Result	
			Comment:	Value below lowest level of quantification (= 0.1 U/L). Set to 0.1 U/L for mean value calculation.			
	17	5	Male	130	ASAT	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			
	17	5	Male	130	Lactate Dehy drogenase	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	4	1	Female	16	Gamma-GT	Result	

Comment: Value below lowest level of quantification (= 0.1 U/L). Set to 0.1 U/L for mean value calculation.

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a1]
Group 1: Control	Mean	64658.6	39774.6
	SD	6727.8	3460.7
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	465027.0**	727036.0**
	SD	68141.1	243939.8
	N	5	5
	%Diff	619.2	1727.9
Group 3: 10 µg/ animal BNT162a1	Mean	304707.0**	222958.2
	SD	34632.5	118385.8
	N	5	5
	%Diff	371.3	460.6
Group 4: 30 µg/ animal BNT162b1	Mean	381868.0**	1434571.0**
	SD	30666.8	522399.7
	N	5	5
	%Diff	490.6	3506.8

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	454853.0**	2143050.0**
	SD	23446.8	71797.8
	N	5	5
	%Diff	603.5	5288.0
Group 6: 30 µg/ animal BNT162c1	Mean	431128.0**	685548.0**
	SD	60320.6	364534.3
	N	5	5
	%Diff	566.8	1623.6
Group 7: 100 µg/ animal BNT162b2	Mean	446781.0**	2159010.0**
	SD	64502.0	78652.0
	N	5	5
	%Diff	591.0	5328.1

[a] - Anova & Dunnett: ** = p ≤ 0.01

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	416278.0 n	545282.5 n
	SD	34413.2	368839.8
	N	10	10
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 1: Control	Mean	50334.7	21233.0
	SD	11962.9	2975.2
	N	10	10
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	429643.0**	551658.5**
	SD	17527.1	201887.8
	N	10	10
	%Diff	753.6	2498.1
Group 3: 10 µg/ animal BNT162a1	Mean	737003.5**	394276.5**
	SD	124583.7	207037.7
	N	10	10
	%Diff	1364.2	1756.9
Group 4: 30 µg/ animal BNT162b1	Mean	437627.0**	930437.0**
	SD	54732.7	608722.2
	N	10	10
	%Diff	769.4	4282.0

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	970915.5**	5927330.0**
	SD	72264.9	2354973.1
	N	10	10
	%Diff	1828.9	27815.7
Group 7: 100 µg/ animal BNT162b2	Mean	1043631.5**	4604490.0**
	SD	80157.0	1488181.0
	N	10	10
	%Diff	1973.4	21585.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	120039.4 n	24501.2 n
	SD	26150.6	8533.2
	N	5	5
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a1]
Group 1: Control	Mean	113897.4	14847.8
	SD	28082.4	4958.1
	N	5	5
	-		
Group 2: 30 µg/ animal BNT162a1	Mean	96757.2	19435.4
	SD	22123.3	4049.4
	N	5	5
	%Diff	-15.0	30.9
Group 3: 10 µg/ animal BNT162a1	Mean	58193.4**	16261.0
	SD	6901.6	5138.0
	N	5	5
	%Diff	-48.9	9.5
Group 4: 30 µg/ animal BNT162b1	Mean	106850.8	20052.6
	SD	19090.7	4943.1
	N	5	5
	%Diff	-6.2	35.1

[a] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a1] - Anova & Dunnett

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	65259.8**	22707.2*
	SD	5082.1	2406.8
	N	5	5
	%Diff	-42.7	52.9
Group 7: 100 µg/ animal BNT162b2	Mean	59438.6**	24303.8*
	SD	5558.8	4950.4
	N	5	5
	%Diff	-47.8	63.7

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a1]
Group 1: Control	Mean	79798.8	18098.2
	SD	17269.9	5486.8
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	401386.0**	126189.4**
	SD	32156.3	63343.9
	N	5	5
	%Diff	403.0	597.2
Group 3: 10 µg/ animal BNT162a1	Mean	323645.0**	57146.0**
	SD	46893.3	15460.1
	N	5	5
	%Diff	305.6	215.8
Group 4: 30 µg/ animal BNT162b1	Mean	378897.0**	330428.0**
	SD	29869.1	292586.3
	N	5	5
	%Diff	374.8	1725.8

[a] - Anova & Dunnett: ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	444957.0**	1639367.0**
	SD	21643.8	557054.1
	N	5	5
	%Diff	457.6	8958.2
Group 6: 30 µg/ animal BNT162c1	Mean	390580.0**	169592.0**
	SD	23209.4	138784.7
	N	5	5
	%Diff	389.5	837.1
Group 7: 100 µg/ animal BNT162b2	Mean	445614.0**	1362630.0**
	SD	27975.1	257962.6
	N	5	5
	%Diff	458.4	7429.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	409704.5 n	134878.1 n
	SD	31388.8	77962.6
	N	10	10
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 1: Control	Mean	52001.7	16055.9
	SD	10058.1	3899.1
	N	10	10
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	467670.5**	269274.2**
	SD	35882.2	133874.6
	N	10	10
	%Diff	799.3	1577.1
Group 3: 10 µg/ animal BNT162a1	Mean	649429.5**	102489.3**
	SD	236844.1	45691.2
	N	10	10
	%Diff	1148.9	538.3
Group 4: 30 µg/ animal BNT162b1	Mean	463014.0**	723981.3**
	SD	31240.3	560182.5
	N	10	10
	%Diff	790.4	4409.1

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	980874.0**	2692160.0**
	SD	86180.9	1082703.5
	N	10	10
	%Diff	1786.2	16667.4
Group 7: 100 µg/ animal BNT162b2	Mean	826053.0**	1937467.5**
	SD	274115.3	1018132.7
	N	10	10
	%Diff	1488.5	11967.0

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	110891.8 n	14755.0 n
	SD	46262.6	4860.1
	N	5	5
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 1: Control	Mean	131519.8	22175.8
	SD	46366.1	12640.6
	N	5	5
	-		
Group 2: 30 µg/ animal BNT162a1	Mean	110365.6	20030.0
	SD	66482.3	7218.8
	N	5	5
	%Diff	-16.1	-9.7
Group 3: 10 µg/ animal BNT162a1	Mean	75601.0	17691.0
	SD	12035.1	3218.6
	N	5	5
	%Diff	-42.5	-20.2
Group 4: 30 µg/ animal BNT162b1	Mean	153412.0	18945.4
	SD	35789.9	5115.2
	N	5	5
	%Diff	16.6	-14.6

[a] - Anova & Dunnett(Log)

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	61578.2*	15699.0
	SD	15860.4	2853.3
	N	5	5
	%Diff	-53.2	-29.2
Group 7: 100 µg/ animal BNT162b2	Mean	90184.8	18626.8
	SD	37898.0	4975.0
	N	5	5
	%Diff	-31.4	-16.0

[a] - Anova & Dunnett: * = p ≤ 0.05

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	5	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	38	3	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	38	5	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Male	Alpha2 Macroglob.	*	Anova & Dunnett: * = p ≤ 0.05
	38	7	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	7	Male	Alpha2 Macroglob.	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	38	5	Female	Alpha1-acid Glycoprotein	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
6	74598	35466
7	58677	40751
8	61115	41545
9	60338	44022
10	68565	37089
Mean	64658.6	39774.6
SD	6727.8	3460.7
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
36	395770	484880
37	412245	585995
38	445750	690305
39	553485	749950
40	517885	1124050
Mean	465027.0	727036.0
SD	68141.1	243939.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
66	346280	377430
67	270970	203495
68	337625	301160
69	281405	77781
70	287255	154925
Mean	304707.0	222958.2
SD	34632.5	118385.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
96	370705	1912550
97	379860	864255
98	430975	1283450
99	346930	2048950
100	380870	1063650
Mean	381868.0	1434571.0
SD	30666.8	522399.7
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
126	431675	2115250
127	447855	2072450
128	436225	2230700
129	485375	2208100
130	473135	2088750
Mean	454853.0	2143050.0
SD	23446.8	71797.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
156	449640	1171250
157	517280	220825
158	440650	541515
159	383510	586840
160	364560	907310
Mean	431128.0	685548.0
SD	60320.6	364534.3
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
186	553550	2173650
187	446970	2280300
188	380375	2071850
189	424225	2111900
190	428785	2157350
Mean	446781.0	2159010.0
SD	64502.0	78652.0
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
151	387715	838040
152	472405	313110
153	457165	1109700
154	416455	102745
155	361605	349125
156	409100	1085600
157	440805	189125
158	382780	234195
159	406110	558865
160	428640	672320
Mean	416278.0	545282.5
SD	34413.2	368839.8
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
1	52385	18903
2	48381	18818
3	38406	18703
4	57563	20376
5	79663	19897
6	51049	23285
7	42368	26508
8	43867	25944
9	39404	18960
10	50261	20936
Mean	50334.7	21233.0
SD	11962.9	2975.2
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
31	416505	229715
32	445745	679065
33	423550	662375
34	455465	351035
35	420835	271255
36	449005	529270
37	397930	649710
38	425580	657965
39	422215	845810
40	439600	640385
Mean	429643.0	551658.5
SD	17527.1	201887.8
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
61	569265	420140
62	830325	513405
63	614150	176050
64	766735	796895
65	698405	123535
66	760240	586800
67	738910	210390
68	1015700	430440
69	653585	270590
70	722720	414520
Mean	737003.5	394276.5
SD	124583.7	207037.7
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
91	427380	891365
92	338995	237575
93	428700	1304000
94	446240	591510
95	442385	515650
96	550585	1503900
97	465035	627240
98	459370	717540
99	434330	2295800
100	383250	619790
Mean	437627.0	930437.0
SD	54732.7	608722.2
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
121	967885	3106700
122	999355	9085700
123	1035755	3212850
124	1106600	4229650
125	855035	4742600
126	986870	5079750
127	896930	4686550
128	966370	8248600
129	906785	8282400
130	987570	8598500
Mean	970915.5	5927330.0
SD	72264.9	2354973.1
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
181	1028100	6341900
182	1138600	6339200
183	1085150	2191950
184	1157050	2305250
185	1057100	5455250
186	876725	5700650
187	968455	4722350
188	1039285	3928800
189	1054500	4971650
190	1031350	4087900
Mean	1043631.5	4604490.0
SD	80157.0	1488181.0
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
161	160530	18377
162	104896	28337
163	118340	36891
164	125305	23605
165	91126	15296
Mean	120039.4	24501.2
SD	26150.6	8533.2
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
11	111670	21367
12	105050	8140
13	74092	12503
14	129530	17146
15	149145	15083
Mean	113897.4	14847.8
SD	28082.4	4958.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
41	99122	24580
42	99224	17621
43	103371	22609
44	60729	17702
45	121340	14665
Mean	96757.2	19435.4
SD	22123.3	4049.4
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
71	67806	7398
72	58939	18308
73	60966	16405
74	50273	20133
75	52983	19061
Mean	58193.4	16261.0
SD	6901.6	5138.0
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
101	112525	15056
102	132825	19432
103	112570	21809
104	84998	27544
105	91336	16422
Mean	106850.8	20052.6
SD	19090.7	4943.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
131	67438	23757
132	73194	22919
133	62850	22600
134	61675	25397
135	61142	18863
Mean	65259.8	22707.2
SD	5082.1	2406.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
191	56500	28453
192	66800	23159
193	56846	18625
194	63641	30314
195	53406	20968
Mean	59438.6	24303.8
SD	5558.8	4950.4
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
21	72103	27364
22	109835	17256
23	66184	15792
24	73415	12823
25	77457	17256
Mean	79798.8	18098.2
SD	17269.9	5486.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
51	453710	127030
52	409260	58599
53	372545	215525
54	388245	155175
55	383170	74618
Mean	401386.0	126189.4
SD	32156.3	63343.9
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
81	260710	81274
82	314615	57579
83	388650	41085
84	342995	46586
85	311255	59206
Mean	323645.0	57146.0
SD	46893.3	15460.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
111	366335	292215
112	366000	115510
113	342730	261475
114	405375	836545
115	414045	146395
Mean	378897.0	330428.0
SD	29869.1	292586.3
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
141	420535	1819650
142	452305	1156100
143	428725	1986800
144	475845	2270400
145	447375	963885
Mean	444957.0	1639367.0
SD	21643.8	557054.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
171	388200	50410
172	425095	409540
173	386875	130920
174	359935	114400
175	392795	142690
Mean	390580.0	169592.0
SD	23209.4	138784.7
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
201	446180	1198200
202	448515	1787900
203	488465	1426900
204	432770	1225650
205	412140	1174500
Mean	445614.0	1362630.0
SD	27975.1	257962.6
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
166	423555	76401
167	454355	65135
168	417625	127105
169	367710	196325
170	381070	150105
171	358060	68208
172	411240	308885
173	427500	183410
174	414135	69107
175	441795	104100
Mean	409704.5	134878.1
SD	31388.8	77962.6
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
16	68688	11887
17	49113	20572
18	42397	19727
19	59898	16584
20	57776	16556
21	55998	22213
22	48929	13657
23	38037	14152
24	39498	9965
25	59683	15246
Mean	52001.7	16055.9
SD	10058.1	3899.1
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
46	516310	383415
47	440495	120600
48	457805	322615
49	432595	56572
50	456585	219120
51	531800	385690
52	463720	227270
53	472725	488200
54	487040	319150
55	417630	170110
Mean	467670.5	269274.2
SD	35882.2	133874.6
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
76	722315	95389
77	692045	114150
78	644855	169520
79	791675	46772
80	927205	142640
81	864770	40796
82	600415	57460
83	772365	97147
84	244590	161820
85	234060	99199
Mean	649429.5	102489.3
SD	236844.1	45691.2
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
106	466190	997090
107	419330	85513
108	533860	1565800
109	468610	599795
110	489860	980535
111	439375	385720
112	445075	115180
113	449440	577540
114	459390	1647550
115	459010	285090
Mean	463014.0	723981.3
SD	31240.3	560182.5
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
136	1072200	2451900
137	983855	3642700
138	823020	812900
139	909230	2210000
140	919480	2527250
141	958720	2256200
142	948335	2975500
143	1034250	3283350
144	1098450	4835050
145	1061200	1926750
Mean	980874.0	2692160.0
SD	86180.9	1082703.5
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
196	993680	1811950
197	1035050	879530
198	811530	2606800
199	1035220	4249000
200	920600	1368850
201	348300	2365000
202	298335	2156150
203	879555	1468150
204	946385	668495
205	991875	1800750
Mean	826053.0	1937467.5
SD	274115.3	1018132.7
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
176	159020	15840
177	92176	14190
178	162220	14064
179	70844	21641
180	70199	8040
Mean	110891.8	14755.0
SD	46262.6	4860.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
26	99854	12361
27	212740	16751
28	106205	17671
29	113690	19838
30	125110	44258
Mean	131519.8	22175.8
SD	46366.1	12640.6
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
56	215790	27646
57	81273	26344
58	125535	10664
59	90135	20242
60	39095	15254
Mean	110365.6	20030.0
SD	66482.3	7218.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
86	92486	15177
87	59378	19022
88	79867	21365
89	73747	19339
90	72527	13552
Mean	75601.0	17691.0
SD	12035.1	3218.6
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
116	207035	18509
117	108505	19144
118	146360	24941
119	162080	10972
120	143080	21161
Mean	153412.0	18945.4
SD	35789.9	5115.2
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
146	76975	17039
147	39454	17000
148	57978	13710
149	56413	11844
150	77071	18902
Mean	61578.2	15699.0
SD	15860.4	2853.3
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
206	60346	26320
207	69090	20888
208	154730	15969
209	92067	14265
210	74691	15692
Mean	90184.8	18626.8
SD	37898.0	4975.0
N	5	5

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	7.23	7.10	12.60	3.00	9.90
	SD	5.60	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.00	15.50	29.20*	3.00 n	9.90 n
	SD	0.00	8.83	26.62	0.00	0.00
	N	3	3	3	3	3
	%Diff	-44.7	118.3	131.7	0.0	0.0
Group 3: 10 µg/ animal BNT162a1	Mean	10.23	7.10	12.60	3.00 n	9.90 n
	SD	10.80	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	41.5	0.0	0.0	0.0	0.0
Group 4: 30 µg/ animal BNT162b1	Mean	4.00	7.10	12.60	3.00 n	9.90 n
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-44.7	0.0	0.0	0.0	0.0

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	4.27	7.10	12.60	3.00 n	9.90 n
100 µg/	SD	0.46	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-41.0	0.0	0.0	0.0	0.0
Group 6:	Mean	7.53	7.10	12.60	3.00 n	9.90 n
30 µg/	SD	6.12	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162c1	%Diff	4.1	0.0	0.0	0.0	0.0
Group 7:	Mean	5.57	7.37	12.60	3.00 n	9.90 n
100 µg/	SD	2.71	0.46	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b2	%Diff	-23.0	3.8	0.0	0.0	0.0

[a] - Anova & Dunnett: n - Inappropriate for statistics

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	99.17	66.10	349.93	12.33	212.37
	SD	7.60	14.69	115.46	8.31	116.87
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	123.47	87.53	464.57	6.80	157.93
	SD	33.70	19.00	114.06	4.59	127.75
	N	3	3	3	3	3
	%Diff	24.5	32.4	32.8	-44.9	-25.6
Group 3: 10 µg/ animal BNT162a1	Mean	80.13	49.33	250.90	3.00*	147.77
	SD	16.85	11.69	64.36	0.00	24.44
	N	3	3	3	3	3
	%Diff	-19.2	-25.4	-28.3	-75.7	-30.4
Group 4: 30 µg/ animal BNT162b1	Mean	82.40	64.43	347.47	9.20	190.77
	SD	11.49	7.01	38.18	1.44	38.89
	N	3	3	3	3	3
	%Diff	-16.9	-2.5	-0.7	-25.4	-10.2

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): * = $p \leq 0.05$

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	92.57	56.07	286.73	3.40	164.13
100 µg/	SD	12.93	15.61	80.42	0.69	39.68
animal	N	3	3	3	3	3
BNT162b1	%Diff	-6.7	-15.2	-18.1	-72.4	-22.7
Group 6:	Mean	89.33	54.97	236.03	3.00*	178.50
30 µg/	SD	4.89	21.21	90.68	0.00	79.72
animal	N	3	3	3	3	3
BNT162c1	%Diff	-9.9	-16.8	-32.5	-75.7	-15.9
Group 7:	Mean	91.33	59.53	285.53	7.37	151.70
100 µg/	SD	16.72	14.54	114.71	7.56	77.90
animal	N	3	3	3	3	3
BNT162b2	%Diff	-7.9	-9.9	-18.4	-40.3	-28.6

[a] - Anova & Dunnett: * = $p \leq 0.05$

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a2]
Group 1: Control	Mean	109.77	92.47	447.53	14.57	365.60
	SD	20.35	19.99	87.14	16.21	74.22
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	59.07	84.57	432.77	6.67	258.53
	SD	50.08	26.63	188.55	3.25	225.11
	N	3	3	3	3	3
	%Diff	-46.2	-8.5	-3.3	-54.2	-29.3
Group 3: 10 µg/ animal BNT162a1	Mean	15.90	8.23*	14.73*	3.00	9.90
	SD	17.02	1.96	3.70	0.00	0.00
	N	3	3	3	3	3
	%Diff	-85.5	-91.1	-96.7	-79.4	-97.3
Group 4: 30 µg/ animal BNT162b1	Mean	22.10	22.13	93.40	3.00	68.67
	SD	30.92	26.04	139.95	0.00	101.79
	N	3	3	3	3	3
	%Diff	-79.9	-76.1	-79.1	-79.4	-81.2

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): * = p ≤ 0.05
[a2] - Anova & Dunnett(Log)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	44.97	39.23	166.93	7.50	121.87
100 µg/	SD	70.96	55.66	267.31	7.79	193.93
animal	N	3	3	3	3	3
BNT162b1	%Diff	-59.0	-57.6	-62.7	-48.5	-66.7
Group 6:	Mean	13.97	16.53	58.63	3.00	18.27
30 µg/	SD	17.26	3.87	26.57	0.00	14.49
animal	N	3	3	3	3	3
BNT162c1	%Diff	-87.3	-82.1	-86.9	-79.4	-95.0
Group 7:	Mean	19.27	16.93	50.83*	3.00	29.27
100 µg/	SD	26.44	17.03	66.22	0.00	33.54
animal	N	3	3	3	3	3
BNT162b2	%Diff	-82.4	-81.7	-88.6	-79.4	-92.0

[a] - Anova & Dunnett: * = $p \leq 0.05$

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	88.43	56.80	269.07	4.50	220.07
	SD	19.95	20.82	111.47	2.60	106.23
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	117.03	75.83	377.60	3.00	191.67
	SD	20.22	18.32	79.12	0.00	56.91
	N	3	3	3	3	3
	%Diff	32.3	33.5	40.3	-33.3	-12.9
Group 3: 10 µg/ animal BNT162a1	Mean	109.40	61.53	344.33	9.10	200.20
	SD	27.17	17.01	107.63	7.04	40.67
	N	3	3	3	3	3
	%Diff	23.7	8.3	28.0	102.2	-9.0
Group 4: 30 µg/ animal BNT162b1	Mean	56.60	41.20	208.17	3.00	84.37
	SD	7.54	13.40	74.37	0.00	86.87
	N	3	3	3	3	3
	%Diff	-36.0	-27.5	-22.6	-33.3	-61.7

[a] - Anova & Dunnett

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	121.47	66.17	364.93	14.40	213.30
100 µg/	SD	12.48	16.50	103.43	10.58	48.88
animal	N	3	3	3	3	3
BNT162b1	%Diff	37.4	16.5	35.6	220.0	-3.1
Group 6:	Mean	110.80	55.23	292.13	4.77	159.30
30 µg/	SD	40.51	6.55	30.04	1.55	8.75
animal	N	3	3	3	3	3
BNT162c1	%Diff	25.3	-2.8	8.6	5.9	-27.6
Group 7:	Mean	92.20	54.60	291.13	7.60	156.00
100 µg/	SD	6.36	13.75	112.49	7.97	92.42
animal	N	3	3	3	3	3
BNT162b2	%Diff	4.3	-3.9	8.2	68.9	-29.1

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 10 Relative to Start Date (48h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	54.97 n	26.17 n	132.93 n	3.00 n	46.77 n
	SD	56.48	27.51	182.48	0.00	63.85
	N	3	3	3	3	3
		-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	84.90	66.80	269.17	3.00	178.57
	SD	61.87	52.44	231.66	0.00	147.46
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	55.63	87.87	362.97	4.63	167.80
	SD	78.85	80.06	383.08	2.83	273.49
	N	3	3	3	3	3
	%Diff	-34.5	31.5	34.8	54.4	-6.0
Group 3: 10 µg/ animal BNT162a1	Mean	4.00	7.10	12.60	3.00	9.90
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-95.3	-89.4	-95.3	0.0	-94.5
Group 4: 30 µg/ animal BNT162b1	Mean	44.80	35.77	145.90	3.00	81.00
	SD	45.08	46.23	230.88	0.00	123.15
	N	3	3	3	3	3
	%Diff	-47.2	-46.5	-45.8	0.0	-54.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	74.53	60.60	302.27	15.10	194.07
100 µg/	SD	63.43	47.90	264.90	11.03	164.25
animal	N	3	3	3	3	3
BNT162b1	%Diff	-12.2	-9.3	12.3	403.3	8.7
Group 7:	Mean	34.43	19.50	57.27	3.00	40.53
100 µg/	SD	32.49	18.80	77.36	0.00	53.06
animal	N	3	3	3	3	3
BNT162b2	%Diff	-59.4	-70.8	-78.7	0.0	-77.3

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	125.33	82.30	381.77	3.53	238.63
	SD	24.16	36.60	149.65	0.92	102.97
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	190.80*	112.80	499.80	3.00	270.73
	SD	35.23	26.42	83.83	0.00	13.59
	N	3	3	3	3	3
	%Diff	52.2	37.1	30.9	-15.1	13.5
Group 3: 10 µg/ animal BNT162a1	Mean	155.60	78.47	381.90	18.27**	225.57
	SD	34.68	18.13	124.92	7.18	54.72
	N	3	3	3	3	3
	%Diff	24.1	-4.7	0.0	417.0	-5.5
Group 4: 30 µg/ animal BNT162b1	Mean	124.07	102.80	471.40	5.37	234.17
	SD	18.46	27.35	129.00	2.05	107.20
	N	3	3	3	3	3
	%Diff	-1.0	24.9	23.5	51.9	-1.9

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	155.27	75.87	353.03	20.10**	233.80
100 µg/	SD	13.54	8.95	40.47	6.67	35.06
animal	N	3	3	3	3	3
BNT162b1	%Diff	23.9	-7.8	-7.5	468.9	-2.0
Group 7:	Mean	119.93	62.93	271.63	11.47	165.80
100 µg/	SD	24.61	12.34	68.69	2.91	35.65
animal	N	3	3	3	3	3
BNT162b2	%Diff	-4.3	-23.5	-28.8	224.5	-30.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a2]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	4.00	7.10	12.60	3.00	9.90
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	111.17*	25.20	69.83	3.00	9.90
	SD	16.10	23.53	84.67	0.00	0.00
	N	3	3	3	3	3
	%Diff	2679.2	254.9	454.2	0.0	0.0
Group 3: 10 µg/ animal BNT162a1	Mean	83.87	7.10	12.60	3.00	9.90
	SD	57.45	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	1996.7	0.0	0.0	0.0	0.0
Group 4: 30 µg/ animal BNT162b1	Mean	31.20	41.97	176.10	7.83	44.70
	SD	47.11	60.39	283.19	8.37	60.28
	N	3	3	3	3	3
	%Diff	680.0	491.1	1297.6	161.1	351.5

[a] - Anova & Dunnett: * = $p \leq 0.05$
[a1] - Anova & Dunnett(Rank)
[a2] - Anova & Dunnett(Log)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	4.00	10.23	22.30	3.00	9.90
100 µg/	SD	0.00	5.43	16.80	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	0.0	44.1	77.0	0.0	0.0
Group 7:	Mean	43.17	44.40	214.23	7.40	106.50
100 µg/	SD	58.33	48.01	289.74	7.62	167.32
animal	N	3	3	3	3	3
BNT162b2	%Diff	979.2	525.4	1600.3	146.7	975.8

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	30.67	28.57	119.00	3.00	71.90
	SD	46.19	23.95	135.10	0.00	107.39
	N	3	3	3	3	3
Group 2: 30 µg/ animal BNT162a1	Mean	4.00	7.10	12.60	3.00 n	9.90
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-87.0	-75.1	-89.4	0.0	-86.2
Group 3: 10 µg/ animal BNT162a1	Mean	9.10	8.00	12.60	3.00 n	9.90
	SD	8.83	1.56	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-70.3	-72.0	-89.4	0.0	-86.2
Group 4: 30 µg/ animal BNT162b1	Mean	8.20	7.10	12.60	3.00 n	9.90
	SD	7.27	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-73.3	-75.1	-89.4	0.0	-86.2

[a] - Anova & Dunnett(Rank): n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	4.00	7.10	12.60	3.00 n	9.90
100 µg/	SD	0.00	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-87.0	-75.1	-89.4	0.0	-86.2
Group 6:	Mean	4.00	7.10	12.60	3.00 n	9.90
30 µg/	SD	0.00	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162c1	%Diff	-87.0	-75.1	-89.4	0.0	-86.2
Group 7:	Mean	22.03	18.43	58.80	3.00 n	43.40
100 µg/	SD	30.80	19.63	80.02	0.00	58.02
animal	N	3	3	3	3	3
BNT162b2	%Diff	-28.2	-35.5	-50.6	0.0	-39.6

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	86.50	65.83	345.70	5.77	168.03
	SD	8.29	29.96	188.07	3.19	78.07
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	97.87	46.83	246.17	6.07	84.67
	SD	32.96	14.73	113.44	4.55	70.78
	N	3	3	3	3	3
	%Diff	13.1	-28.9	-28.8	5.2	-49.6
Group 3: 10 µg/ animal BNT162a1	Mean	86.40	51.03	260.87	3.00	114.70
	SD	19.75	11.57	62.68	0.00	26.97
	N	3	3	3	3	3
	%Diff	-0.1	-22.5	-24.5	-48.0	-31.7
Group 4: 30 µg/ animal BNT162b1	Mean	73.37	46.73	235.47	5.50	132.57
	SD	29.11	8.39	52.21	4.07	27.24
	N	3	3	3	3	3
	%Diff	-15.2	-29.0	-31.9	-4.6	-21.1

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	68.80	38.03	191.43	3.00	90.77
100 µg/	SD	11.61	4.62	36.49	0.00	33.29
animal	N	3	3	3	3	3
BNT162b1	%Diff	-20.5	-42.2	-44.6	-48.0	-46.0
Group 6:	Mean	104.33	67.03	298.10	4.27	209.23
30 µg/	SD	11.41	8.89	13.67	2.19	40.58
animal	N	3	3	3	3	3
BNT162c1	%Diff	20.6	1.8	-13.8	-26.0	24.5
Group 7:	Mean	88.10	52.83	268.23	3.43	182.03
100 µg/	SD	10.64	11.39	67.42	0.75	51.88
animal	N	3	3	3	3	3
BNT162b2	%Diff	1.8	-19.7	-22.4	-40.5	8.3

[a] - Anova & Dunnett

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	23.27	12.80	48.37	3.00	17.80
	SD	31.91	9.87	61.95	0.00	13.68
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	31.00	27.47	126.83	3.00 n	74.30
	SD	46.25	35.28	197.86	0.00	111.54
	N	3	3	3	3	3
	%Diff	33.2	114.6	162.2	0.0	317.4
Group 3: 10 µg/ animal BNT162a1	Mean	27.20	12.80	41.77	3.00 n	9.90
	SD	24.15	8.94	41.12	0.00	0.00
	N	3	3	3	3	3
	%Diff	16.9	0.0	-13.6	0.0	-44.4
Group 4: 30 µg/ animal BNT162b1	Mean	54.43	34.17	148.90	3.00 n	112.93
	SD	39.53	46.88	236.08	0.00	178.46
	N	3	3	3	3	3
	%Diff	134.0	166.9	207.9	0.0	534.5

[a] - Anova & Dunnett(Log)
[a1] - Anova & Dunnett(Rank): n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	44.73	35.73	156.30	3.00 n	105.33
100 µg/	SD	68.48	49.59	248.90	0.00	165.30
animal	N	3	3	3	3	3
BNT162b1	%Diff	92.3	179.2	223.2	0.0	491.8
Group 6:	Mean	9.50	7.50	12.60	3.00 n	9.90
30 µg/	SD	8.26	0.69	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162c1	%Diff	-59.2	-41.4	-73.9	0.0	-44.4
Group 7:	Mean	4.60	7.43	12.60	3.00 n	9.90
100 µg/	SD	1.04	0.58	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b2	%Diff	-80.2	-41.9	-73.9	0.0	-44.4

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	77.80	43.67	213.37	3.00	125.70
	SD	18.19	19.70	99.74	0.00	98.90
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	103.77	42.77	220.37	3.00	115.83
	SD	53.24	23.93	146.31	0.00	92.56
	N	3	3	3	3	3
	%Diff	33.4	-2.1	3.3	0.0	-7.8
Group 3: 10 µg/ animal BNT162a1	Mean	129.80	70.53	400.23	7.03	209.87
	SD	11.86	12.55	95.18	3.65	25.81
	N	3	3	3	3	3
	%Diff	66.8	61.5	87.6	134.4	67.0
Group 4: 30 µg/ animal BNT162b1	Mean	80.93	51.47	260.00	3.00	202.23
	SD	30.62	14.82	89.54	0.00	86.64
	N	3	3	3	3	3
	%Diff	4.0	17.9	21.9	0.0	60.9

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	118.27	77.73	445.93	4.67	240.53
100 µg/	SD	7.21	10.64	51.50	2.31	38.91
animal	N	3	3	3	3	3
BNT162b1	%Diff	52.0	78.0	109.0	55.6	91.4
Group 6:	Mean	164.30**	60.17	345.67	6.43	179.00
30 µg/	SD	17.38	13.33	109.37	2.47	85.78
animal	N	3	3	3	3	3
BNT162c1	%Diff	111.2	37.8	62.0	114.4	42.4
Group 7:	Mean	118.40	68.07	378.43	8.03	205.53
100 µg/	SD	24.66	13.95	92.07	4.74	37.46
animal	N	3	3	3	3	3
BNT162b2	%Diff	52.2	55.9	77.4	167.8	63.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 10 Relative to Start Date (48h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	80.67 n	7.10 n	12.60 n	3.00 n	9.90 n
	SD	49.37	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
		-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a2]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	37.33	26.27	116.57	3.00	66.90
	SD	57.74	33.20	180.08	0.00	98.73
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	79.63	60.53	252.57	3.00	148.53
	SD	23.68	39.81	182.59	0.00	120.84
	N	3	3	3	3	3
	%Diff	113.3	130.5	116.7	0.0	122.0
Group 3: 10 µg/ animal BNT162a1	Mean	55.60	42.73	179.63	12.23	101.57
	SD	62.22	48.76	243.56	15.99	158.77
	N	3	3	3	3	3
	%Diff	48.9	62.7	54.1	307.8	51.8
Group 4: 30 µg/ animal BNT162b1	Mean	34.30	7.10	12.60	3.00	9.90
	SD	36.98	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-8.1	-73.0	-89.2	0.0	-85.2

[a] - Anova & Dunnett(Log)
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	19.07	7.10	12.60	3.00	9.90
100 µg/	SD	26.10	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-48.9	-73.0	-89.2	0.0	-85.2
Group 7:	Mean	47.63	42.37	203.97	10.70	112.73
100 µg/	SD	66.67	61.08	331.46	13.34	178.11
animal	N	3	3	3	3	3
BNT162b2	%Diff	27.6	61.3	75.0	256.7	68.5

[a] - Anova & Dunnett

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	121.37	90.97	420.53	3.27	230.10
	SD	18.61	29.50	143.71	0.46	89.38
	N	3	3	3	3	3
Group 2: 30 µg/ animal BNT162a1	Mean	185.67	96.20	468.70	3.10	246.37
	SD	51.68	23.88	100.85	0.17	46.35
	N	3	3	3	3	3
	%Diff	53.0	5.8	11.5	-5.1	7.1
Group 3: 10 µg/ animal BNT162a1	Mean	158.37	72.50	344.87	13.27	213.67
	SD	27.58	1.15	40.45	9.35	5.06
	N	3	3	3	3	3
	%Diff	30.5	-20.3	-18.0	306.1	-7.1
Group 4: 30 µg/ animal BNT162b1	Mean	134.57	108.27	504.70	3.67	253.23
	SD	23.73	26.68	112.68	0.61	35.48
	N	3	3	3	3	3
	%Diff	10.9	19.0	20.0	12.2	10.1

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	133.50	97.77	488.37	19.00*	277.20
100 µg/	SD	8.85	18.01	138.53	12.20	66.15
animal	N	3	3	3	3	3
BNT162b1	%Diff	10.0	7.5	16.1	481.6	20.5
Group 7:	Mean	112.23	64.93	314.80	11.37	186.23
100 µg/	SD	13.20	16.36	106.20	9.11	55.96
animal	N	3	3	3	3	3
BNT162b2	%Diff	-7.5	-28.6	-25.1	248.0	-19.1

[a] - Anova & Dunnett: * = $p \leq 0.05$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	32.37	20.03	77.83	3.00	45.87
	SD	49.13	22.40	112.99	0.00	62.30
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	143.07*	26.20	97.60	6.10	91.10
	SD	28.57	33.08	147.22	5.37	140.64
	N	3	3	3	3	3
	%Diff	342.0	30.8	25.4	103.3	98.6
Group 3: 10 µg/ animal BNT162a1	Mean	68.70	7.10	12.60	3.00	9.90
	SD	36.25	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	112.3	-64.6	-83.8	0.0	-78.4
Group 4: 30 µg/ animal BNT162b1	Mean	14.73	7.10	12.60	3.00	9.90
	SD	18.59	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-54.5	-64.6	-83.8	0.0	-78.4

[a] - Anova & Dunnett(Log): * = $p \leq 0.05$
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	10.43	11.40	24.87	3.00	9.90
100 µg/	SD	9.87	6.60	19.54	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-67.8	-43.1	-68.1	0.0	-78.4
Group 7:	Mean	4.70	7.10	12.60	3.00	9.90
100 µg/	SD	0.82	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b2	%Diff	-85.5	-64.6	-83.8	0.0	-78.4

[a] - Anova & Dunnett

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TABLE 9-1 Cytokine Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	1 (PreDs)	2	Male	IL-1beta	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	1 (PreDs)	2	Male	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	2	Male	IL-10	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	3	Male	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	3	Male	IL-10	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	4	Male	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	4	Male	IL-10	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	5	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	5	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	6	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	6	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	7	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	7	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (6 h pa)	3	Male	IL-6	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	1 (6 h pa)	6	Male	IL-6	*	Anova & Dunnett: * = p ≤ 0.05
	8 (PreDs)	3	Male	TNF-alpha	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	8 (PreDs)	3	Male	IL-1beta	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	8 (PreDs)	7	Male	IL-1beta	*	Anova & Dunnett: * = p ≤ 0.05
	10 (48h pa)	6	Male	IFN-gamma	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	TNF-alpha	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	IL-1beta	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	15 (6 h pa)	2	Male	IFN-gamma	*	Anova & Dunnett: * = p ≤ 0.05
	15 (6 h pa)	3	Male	IL-6	**	Anova & Dunnett: ** = p ≤ 0.01
	15 (6 h pa)	5	Male	IL-6	**	Anova & Dunnett: ** = p ≤ 0.01
	17 (48h pa)	2	Male	IFN-gamma	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 9-1 Cytokine Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	1 (PreDs)	2	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	3	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	4	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	5	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	6	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	7	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (PreDs)	2	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	8 (PreDs)	3	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	8 (PreDs)	4	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	8 (PreDs)	5	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (PreDs)	6	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (PreDs)	7	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (6 h pa)	6	Female	IFN-gamma	**	Anova & Dunnett: ** = $p \leq 0.01$
	10 (48h pa)	6	Female	IFN-gamma	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	TNF-alpha	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	IL-1beta	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	15 (6 h pa)	5	Female	IL-6	*	Anova & Dunnett: * = $p \leq 0.05$
	17 (48h pa)	2	Female	IFN-gamma	*	Anova & Dunnett(Log): * = $p \leq 0.05$

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
212	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
213	13.7	7.1 !	12.6 !	3.0 !	9.9 !
Mean	7.23	7.10	12.60	3.00	9.90
SD	5.60	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
218	4.0 !	14.7	15.1	3.0 !	9.9 !
219	4.0 !	24.7	59.9	3.0 !	9.9 !
Mean	4.00	15.50	29.20	3.00	9.90
SD	0.00	8.83	26.62	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
224	22.7	7.1 !	12.6 !	3.0 !	9.9 !
225	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	10.23	7.10	12.60	3.00	9.90
SD	10.80	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
230	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
231	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
236	4.8	7.1 !	12.6 !	3.0 !	9.9 !
237	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.27	7.10	12.60	3.00	9.90
SD	0.46	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
242	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
243	14.6	7.1 !	12.6 !	3.0 !	9.9 !
Mean	7.53	7.10	12.60	3.00	9.90
SD	6.12	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	8.7	7.1 !	12.6 !	3.0 !	9.9 !
248	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
249	4.0 !	7.9	12.6 !	3.0 !	9.9 !
Mean	5.57	7.37	12.60	3.00	9.90
SD	2.71	0.46	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	93.5	60.8	316.2	8.2	149.9
212	96.2	54.8	255.1	6.9	140.0
213	107.8	82.7	478.5	21.9	347.2
Mean	99.17	66.10	349.93	12.33	212.37
SD	7.60	14.69	115.46	8.31	116.87
N	3	3	3	3	3

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	148.7	88.0	505.9	11.9	304.4
218	136.5	106.3	552.2	5.5	99.9
219	85.2	68.3	335.6	3.0 !	69.5
Mean	123.47	87.53	464.57	6.80	157.93
SD	33.70	19.00	114.06	4.59	127.75
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	83.1	54.9	286.5	3.0 !	149.3
224	62.0	35.9	176.6	3.0 !	122.6
225	95.3	57.2	289.6	3.0 !	171.4
Mean	80.13	49.33	250.90	3.00	147.77
SD	16.85	11.69	64.36	0.00	24.44
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	94.8	63.4	338.3	9.6	153.5
230	80.3	71.9	389.4	10.4	231.1
231	72.1	58.0	314.7	7.6	187.7
Mean	82.40	64.43	347.47	9.20	190.77
SD	11.49	7.01	38.18	1.44	38.89
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	87.3	51.7	279.8	3.0 !	180.4
236	107.3	73.4	370.4	4.2	193.1
237	83.1	43.1	210.0	3.0 !	118.9
Mean	92.57	56.07	286.73	3.40	164.13
SD	12.93	15.61	80.42	0.69	39.68
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	90.4	32.6	143.3	3.0 !	97.9
242	93.6	57.5	240.3	3.0 !	180.3
243	84.0	74.8	324.5	3.0 !	257.3
Mean	89.33	54.97	236.03	3.00	178.50
SD	4.89	21.21	90.68	0.00	79.72
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	107.6	75.9	416.4	16.1	229.1
248	92.2	48.1	237.8	3.0 !	152.7
249	74.2	54.6	202.4	3.0 !	73.3
Mean	91.33	59.53	285.53	7.37	151.70
SD	16.72	14.54	114.71	7.56	77.90
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	90.7	71.5	349.6	3.0 !	279.9
212	107.4	94.6	476.5	7.6	408.8
213	131.2	111.3	516.5	33.1	408.1
Mean	109.77	92.47	447.53	14.57	365.60
SD	20.35	19.99	87.14	16.21	74.22
N	3	3	3	3	3

! = Result Comment

Document 1

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	71.3	80.5	446.1	7.8	317.2
218	101.9	113.0	614.3	9.2	448.5
219	4.0 !	60.2	237.9	3.0 !	9.9 !
Mean	59.07	84.57	432.77	6.67	258.53
SD	50.08	26.63	188.55	3.25	225.11
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	7.3	7.1 !	12.6 !	3.0 !	9.9 !
224	4.9	7.1 !	12.6 !	3.0 !	9.9 !
225	35.5	10.5	19.0	3.0 !	9.9 !
Mean	15.90	8.23	14.73	3.00	9.90
SD	17.02	1.96	3.70	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
230	4.5	7.1 !	12.6 !	3.0 !	9.9 !
231	57.8	52.2	255.0	3.0 !	186.2
Mean	22.10	22.13	93.40	3.00	68.67
SD	30.92	26.04	139.95	0.00	101.79
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
236	126.9	103.5	475.6	16.5	345.8
237	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	44.97	39.23	166.93	7.50	121.87
SD	70.96	55.66	267.31	7.79	193.93
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	33.9	21.0	88.8	3.0 !	35.0
242	4.0 !	14.3	48.4	3.0 !	9.9 !
243	4.0 !	14.3	38.7	3.0 !	9.9 !
Mean	13.97	16.53	58.63	3.00	18.27
SD	17.26	3.87	26.57	0.00	14.49
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	49.8	36.6	127.3	3.0 !	68.0
248	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
249	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	19.27	16.93	50.83	3.00	29.27
SD	26.44	17.03	66.22	0.00	33.54
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	80.1	47.1	228.7	3.0 !	179.5
212	74.0	42.6	183.4	3.0 !	140.1
213	111.2	80.7	395.1	7.5	340.6
Mean	88.43	56.80	269.07	4.50	220.07
SD	19.95	20.82	111.47	2.60	106.23
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	116.1	59.1	297.4	3.0 !	192.6
218	137.7	73.0	379.8	3.0 !	248.1
219	97.3	95.4	455.6	3.0 !	134.3
Mean	117.03	75.83	377.60	3.00	191.67
SD	20.22	18.32	79.12	0.00	56.91
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	139.0	78.2	446.4	16.8	238.2
224	85.6	44.2	231.9	3.0 !	157.3
225	103.6	62.2	354.7	7.5	205.1
Mean	109.40	61.53	344.33	9.10	200.20
SD	27.17	17.01	107.63	7.04	40.67
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	58.8	37.7	188.8	3.0 !	9.9 !
230	62.8	56.0	290.3	3.0 !	179.8
231	48.2	29.9	145.4	3.0 !	63.4
Mean	56.60	41.20	208.17	3.00	84.37
SD	7.54	13.40	74.37	0.00	86.87
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	112.4	73.3	394.3	16.3	246.7
236	135.7	77.9	450.5	23.9	236.0
237	116.3	47.3	250.0	3.0 !	157.2
Mean	121.47	66.17	364.93	14.40	213.30
SD	12.48	16.50	103.43	10.58	48.88
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	109.8	49.2	261.2	3.0 !	164.4
242	151.8	62.2	321.2	5.9	149.2
243	70.8	54.3	294.0	5.4	164.3
Mean	110.80	55.23	292.13	4.77	159.30
SD	40.51	6.55	30.04	1.55	8.75
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	98.4	69.7	412.4	16.8	254.7
248	85.7	51.3	270.8	3.0 !	141.8
249	92.5	42.8	190.2	3.0 !	71.5
Mean	92.20	54.60	291.13	7.60	156.00
SD	6.36	13.75	112.49	7.97	92.42
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date (48h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	116.3	57.7	342.9	3.0 !	120.5
242	43.5	7.1 !	12.6 !	3.0 !	9.9 !
243	5.1	13.7	43.3	3.0 !	9.9 !
Mean	54.97	26.17	132.93	3.00	46.77
SD	56.48	27.51	182.48	0.00	63.85
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	130.6	105.4	463.0	3.0 !	283.1
212	109.6	87.9	331.9	3.0 !	242.7
213	14.5	7.1 !	12.6 !	3.0 !	9.9 !
Mean	84.90	66.80	269.17	3.00	178.57
SD	61.87	52.44	231.66	0.00	147.46
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	6.9	7.1 !	12.6 !	3.0 !	9.9 !
218	146.6	167.2	772.0	7.9	483.6
219	13.4	89.3	304.3	3.0 !	9.9 !
Mean	55.63	87.87	362.97	4.63	167.80
SD	78.85	80.06	383.08	2.83	273.49
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
224	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
225	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	37.2	11.1	12.6 !	3.0 !	9.9 !
230	93.2	89.1	412.5	3.0 !	223.2
231	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	44.80	35.77	145.90	3.00	81.00
SD	45.08	46.23	230.88	0.00	123.15
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	92.7	75.2	362.0	17.7	246.9
236	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
237	126.9	99.5	532.2	24.6	325.4
Mean	74.53	60.60	302.27	15.10	194.07
SD	63.43	47.90	264.90	11.03	164.25
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	69.9	41.2	146.6	3.0 !	101.8
248	6.1	8.1	12.6 !	3.0 !	9.9 !
249	27.3	9.2	12.6 !	3.0 !	9.9 !
Mean	34.43	19.50	57.27	3.00	40.53
SD	32.49	18.80	77.36	0.00	53.06
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	124.7	67.4	302.0	3.0 !	203.8
212	101.5	55.5	288.9	3.0 !	157.6
213	149.8	124.0	554.4	4.6	354.5
Mean	125.33	82.30	381.77	3.53	238.63
SD	24.16	36.60	149.65	0.92	102.97
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	230.7	91.6	419.3	3.0 !	260.3
218	164.0	104.4	493.5	3.0 !	265.8
219	177.7	142.4	586.6	3.0 !	286.1
Mean	190.80	112.80	499.80	3.00	270.73
SD	35.23	26.42	83.83	0.00	13.59
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	116.8	64.0	301.3	15.6	196.2
224	183.6	72.6	318.6	12.8	191.8
225	166.4	98.8	525.8	26.4	288.7
Mean	155.60	78.47	381.90	18.27	225.57
SD	34.68	18.13	124.92	7.18	54.72
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	135.9	102.5	477.2	6.6	181.6
230	133.5	130.3	597.4	6.5	357.5
231	102.8	75.6	339.6	3.0 !	163.4
Mean	124.07	102.80	471.40	5.37	234.17
SD	18.46	27.35	129.00	2.05	107.20
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	140.2	83.2	395.2	23.7	273.6
236	159.2	78.5	349.4	24.2	220.3
237	166.4	65.9	314.5	12.4	207.5
Mean	155.27	75.87	353.03	20.10	233.80
SD	13.54	8.95	40.47	6.67	35.06
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	92.3	49.2	197.1	12.4	165.7
248	139.5	73.1	332.4	13.8	201.5
249	128.0	66.5	285.4	8.2	130.2
Mean	119.93	62.93	271.63	11.47	165.80
SD	24.61	12.34	68.69	2.91	35.65
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
212	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
213	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	94.9	16.7	29.8	3.0 !	9.9 !
218	111.5	7.1 !	12.6 !	3.0 !	9.9 !
219	127.1	51.8	167.1	3.0 !	9.9 !
Mean	111.17	25.20	69.83	3.00	9.90
SD	16.10	23.53	84.67	0.00	0.00
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	22.9	7.1 !	12.6 !	3.0 !	9.9 !
224	137.0	7.1 !	12.6 !	3.0 !	9.9 !
225	91.7	7.1 !	12.6 !	3.0 !	9.9 !
Mean	83.87	7.10	12.60	3.00	9.90
SD	57.45	0.00	0.00	0.00	0.00
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
230	85.6	111.7	503.1	17.5	114.3
231	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	31.20	41.97	176.10	7.83	44.70
SD	47.11	60.39	283.19	8.37	60.28
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
236	4.0 !	16.5	41.7	3.0 !	9.9 !
237	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	10.23	22.30	3.00	9.90
SD	0.00	5.43	16.80	0.00	0.00
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	110.2	99.8	547.6	16.2	299.7
248	4.0 !	15.0	23.1	3.0 !	9.9 !
249	15.3	18.4	72.0	3.0 !	9.9 !
Mean	43.17	44.40	214.23	7.40	106.50
SD	58.33	48.01	289.74	7.62	167.32
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	84.0	54.4	271.0	3.0 !	195.9
216	4.0 !	24.2	73.4	3.0 !	9.9 !
Mean	30.67	28.57	119.00	3.00	71.90
SD	46.19	23.95	135.10	0.00	107.39
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
221	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
222	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	19.3	9.8	12.6 !	3.0 !	9.9 !
227	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
228	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	9.10	8.00	12.60	3.00	9.90
SD	8.83	1.56	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
233	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
234	16.6	7.1 !	12.6 !	3.0 !	9.9 !
Mean	8.20	7.10	12.60	3.00	9.90
SD	7.27	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
239	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
240	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
245	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
246	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	4.5	7.1 !	12.6 !	3.0 !	9.9 !
251	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
252	57.6	41.1	151.2	3.0 !	110.4
Mean	22.03	18.43	58.80	3.00	43.40
SD	30.80	19.63	80.02	0.00	58.02
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	77.0	38.9	190.9	3.4	83.6
215	92.3	60.5	291.2	4.5	237.6
216	90.2	98.1	555.0	9.4	182.9
Mean	86.50	65.83	345.70	5.77	168.03
SD	8.29	29.96	188.07	3.19	78.07
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	100.2	41.9	195.6	3.9	40.5
221	63.8	35.2	166.8	3.0 !	47.2
222	129.6	63.4	376.1	11.3	166.3
Mean	97.87	46.83	246.17	6.07	84.67
SD	32.96	14.73	113.44	4.55	70.78
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	71.9	55.0	270.3	3.0 !	103.9
227	108.9	60.1	318.3	3.0 !	145.4
228	78.4	38.0	194.0	3.0 !	94.8
Mean	86.40	51.03	260.87	3.00	114.70
SD	19.75	11.57	62.68	0.00	26.97
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	81.7	48.5	230.7	3.0 !	146.2
233	41.0	37.6	185.8	3.3	101.2
234	97.4	54.1	289.9	10.2	150.3
Mean	73.37	46.73	235.47	5.50	132.57
SD	29.11	8.39	52.21	4.07	27.24
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	67.0	34.3	168.3	3.0 !	76.6
239	81.2	43.2	233.5	3.0 !	128.8
240	58.2	36.6	172.5	3.0 !	66.9
Mean	68.80	38.03	191.43	3.00	90.77
SD	11.61	4.62	36.49	0.00	33.29
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	103.8	60.7	291.7	3.0 !	227.0
245	93.2	63.2	288.8	6.8	162.8
246	116.0	77.2	313.8	3.0 !	237.9
Mean	104.33	67.03	298.10	4.27	209.23
SD	11.41	8.89	13.67	2.19	40.58
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	99.6	65.9	345.8	4.3	237.8
251	78.6	45.0	223.7	3.0 !	173.1
252	86.1	47.6	235.2	3.0 !	135.2
Mean	88.10	52.83	268.23	3.43	182.03
SD	10.64	11.39	67.42	0.75	51.88
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	60.1	24.2	119.9	3.0 !	33.6
216	5.7	7.1 !	12.6 !	3.0 !	9.9 !
Mean	23.27	12.80	48.37	3.00	17.80
SD	31.91	9.87	61.95	0.00	13.68
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	84.4	68.2	355.3	3.0 !	203.1
221	4.6	7.1 !	12.6 !	3.0 !	9.9 !
222	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	31.00	27.47	126.83	3.00	74.30
SD	46.25	35.28	197.86	0.00	111.54
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	25.4	8.2	23.9	3.0 !	9.9 !
227	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
228	52.2	23.1	88.8	3.0 !	9.9 !
Mean	27.20	12.80	41.77	3.00	9.90
SD	24.15	8.94	41.12	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	89.7	88.3	421.5	3.0 !	319.0
233	11.7	7.1 !	12.6 !	3.0 !	9.9 !
234	61.9	7.1 !	12.6 !	3.0 !	9.9 !
Mean	54.43	34.17	148.90	3.00	112.93
SD	39.53	46.88	236.08	0.00	178.46
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	6.4	7.1 !	12.6 !	3.0 !	9.9 !
239	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
240	123.8	93.0	443.7	3.0 !	296.2
Mean	44.73	35.73	156.30	3.00	105.33
SD	68.48	49.59	248.90	0.00	165.30
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	5.5	7.1 !	12.6 !	3.0 !	9.9 !
245	19.0	8.3	12.6 !	3.0 !	9.9 !
246	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	9.50	7.50	12.60	3.00	9.90
SD	8.26	0.69	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
251	5.8	8.1	12.6 !	3.0 !	9.9 !
252	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.60	7.43	12.60	3.00	9.90
SD	1.04	0.58	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	86.4	56.6	270.2	3.0 !	183.4
215	56.9	21.0	98.2	3.0 !	11.5
216	90.1	53.4	271.7	3.0 !	182.2
Mean	77.80	43.67	213.37	3.00	125.70
SD	18.19	19.70	99.74	0.00	98.90
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	118.9	50.6	278.1	3.0 !	156.5
221	44.6	15.9	54.0	3.0 !	9.9 !
222	147.8	61.8	329.0	3.0 !	181.1
Mean	103.77	42.77	220.37	3.00	115.83
SD	53.24	23.93	146.31	0.00	92.56
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	131.2	83.9	503.1	10.1	238.5
227	140.9	68.7	382.3	8.0	202.7
228	117.3	59.0	315.3	3.0 !	188.4
Mean	129.80	70.53	400.23	7.03	209.87
SD	11.86	12.55	95.18	3.65	25.81
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	92.1	58.0	327.0	3.0 !	228.5
233	46.3	34.5	158.3	3.0 !	105.5
234	104.4	61.9	294.7	3.0 !	272.7
Mean	80.93	51.47	260.00	3.00	202.23
SD	30.62	14.82	89.54	0.00	86.64
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	110.2	81.6	450.5	7.3	245.2
239	120.5	85.9	495.0	3.0 !	276.9
240	124.1	65.7	392.3	3.7	199.5
Mean	118.27	77.73	445.93	4.67	240.53
SD	7.21	10.64	51.50	2.31	38.91
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	156.6	63.8	364.5	8.1	219.2
245	152.1	45.4	228.1	3.6	80.5
246	184.2	71.3	444.4	7.6	237.3
Mean	164.30	60.17	345.67	6.43	179.00
SD	17.38	13.33	109.37	2.47	85.78
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	95.8	54.1	297.9	12.4	162.6
251	144.7	82.0	478.8	8.7	231.6
252	114.7	68.1	358.6	3.0 !	222.4
Mean	118.40	68.07	378.43	8.03	205.53
SD	24.66	13.95	92.07	4.74	37.46
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date (48h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	137.0	7.1 !	12.6 !	3.0 !	9.9 !
245	44.9	7.1 !	12.6 !	3.0 !	9.9 !
246	60.1	7.1 !	12.6 !	3.0 !	9.9 !
Mean	80.67	7.10	12.60	3.00	9.90
SD	49.37	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	104.0	64.6	324.5	3.0 !	180.9
216	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	37.33	26.27	116.57	3.00	66.90
SD	57.74	33.20	180.08	0.00	98.73
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	104.0	96.9	382.5	3.0 !	231.6
221	78.2	66.7	331.4	3.0 !	204.1
222	56.7	18.0	43.8	3.0 !	9.9 !
Mean	79.63	60.53	252.57	3.00	148.53
SD	23.68	39.81	182.59	0.00	120.84
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	38.1	22.8	67.2	3.0 !	9.9 !
227	124.7	98.3	459.1	30.7	284.9
228	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	55.60	42.73	179.63	12.23	101.57
SD	62.22	48.76	243.56	15.99	158.77
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	23.4	7.1 !	12.6 !	3.0 !	9.9 !
233	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
234	75.5	7.1 !	12.6 !	3.0 !	9.9 !
Mean	34.30	7.10	12.60	3.00	9.90
SD	36.98	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	49.2	7.1 !	12.6 !	3.0 !	9.9 !
239	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
240	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	19.07	7.10	12.60	3.00	9.90
SD	26.10	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

Document 1

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	124.4	112.9	586.7	26.1	318.4
251	14.3	7.1 !	12.6 !	3.0 !	9.9 !
252	4.2	7.1 !	12.6 !	3.0 !	9.9 !
Mean	47.63	42.37	203.97	10.70	112.73
SD	66.67	61.08	331.46	13.34	178.11
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	139.7	118.6	565.1	3.8	330.2
215	102.5	59.9	277.7	3.0 !	158.3
216	121.9	94.4	418.8	3.0 !	201.8
Mean	121.37	90.97	420.53	3.27	230.10
SD	18.61	29.50	143.71	0.46	89.38
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	236.3	116.3	536.5	3.0 !	255.3
221	133.0	69.8	352.8	3.0 !	196.2
222	187.7	102.5	516.8	3.3	287.6
Mean	185.67	96.20	468.70	3.10	246.37
SD	51.68	23.88	100.85	0.17	46.35
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	150.6	73.4	391.2	15.5	211.0
227	189.0	72.9	316.6	21.3	219.5
228	135.5	71.2	326.8	3.0 !	210.5
Mean	158.37	72.50	344.87	13.27	213.67
SD	27.58	1.15	40.45	9.35	5.06
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	139.1	130.8	595.5	3.0 !	272.3
233	108.9	78.8	378.6	4.2	212.3
234	155.7	115.2	540.0	3.8	275.1
Mean	134.57	108.27	504.70	3.67	253.23
SD	23.73	26.68	112.68	0.61	35.48
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	123.7	77.1	328.8	13.4	207.7
239	135.9	106.1	558.4	10.6	284.5
240	140.9	110.1	577.9	33.0	339.4
Mean	133.50	97.77	488.37	19.00	277.20
SD	8.85	18.01	138.53	12.20	66.15
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	119.3	81.6	421.2	21.8	247.9
251	120.4	64.3	314.4	7.3	172.1
252	97.0	48.9	208.8	5.0	138.7
Mean	112.23	64.93	314.80	11.37	186.23
SD	13.20	16.36	106.20	9.11	55.96
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	89.1	45.9	208.3	3.0 !	117.8
216	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	32.37	20.03	77.83	3.00	45.87
SD	49.13	22.40	112.99	0.00	62.30
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	169.1	7.1 !	12.6 !	3.0 !	9.9 !
221	112.5	64.4	267.6	12.3	253.5
222	147.6	7.1 !	12.6 !	3.0 !	9.9 !
Mean	143.07	26.20	97.60	6.10	91.10
SD	28.57	33.08	147.22	5.37	140.64
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	68.6	7.1 !	12.6 !	3.0 !	9.9 !
227	32.5	7.1 !	12.6 !	3.0 !	9.9 !
228	105.0	7.1 !	12.6 !	3.0 !	9.9 !
Mean	68.70	7.10	12.60	3.00	9.90
SD	36.25	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
233	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
234	36.2	7.1 !	12.6 !	3.0 !	9.9 !
Mean	14.73	7.10	12.60	3.00	9.90
SD	18.59	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	21.8	8.1	14.6	3.0 !	9.9 !
239	5.5	19.0	47.4	3.0 !	9.9 !
240	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	10.43	11.40	24.87	3.00	9.90
SD	9.87	6.60	19.54	0.00	0.00
N	3	3	3	3	3

! = Result Comment

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	5.6	7.1 !	12.6 !	3.0 !	9.9 !
251	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
252	4.5	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.70	7.10	12.60	3.00	9.90
SD	0.82	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	1	Male	211	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	2	Male	217	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	218	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	218	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	219	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	5	Male	235	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	6	Male	241	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	247	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	247	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	7	Male	247	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	247	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (6 h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (6 h pa)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Male	219	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	230	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	4	Male	230	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	230	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	242	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	242	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	243	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	243	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	247	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	249	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	7	Male	249	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	249	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	249	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (6 h pa)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (6 h pa)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	243	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	213	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	1	Male	213	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	213	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	213	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	3	Male	224	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	4	Male	231	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	247	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	248	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	7	Male	249	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	249	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	1	Male	212	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	217	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	218	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	218	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	218	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	225	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	225	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	5	Male	235	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	236	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	236	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	236	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	7	Male	248	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	7	Male	249	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	17 (48h pa)	7	Male	249	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
					Comments and Markers		
	1 (PreDs)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	216	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	1	Female	216	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	220	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	220	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	220	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	220	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	2	Female	221	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	226	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	227	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	3	Female	227	TNF-alpha	Result	
	Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	227	IL-1beta	Result	
	Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	227	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	227	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	228	IFN-gamma	Result	
	Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	228	TNF-alpha	Result	
	Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	228	IL-1beta	Result	
	Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	228	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	1 (PreDs)	3	Female	228	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	232	IFN-gamma	Result	
	Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	232	TNF-alpha	Result	
	Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	232	IL-1beta	Result	
	Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	232	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	232	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	4	Female	233	IFN-gamma	Result	
	Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	233	TNF-alpha	Result	
	Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	233	IL-1beta	Result	
	Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	233	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	233	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	234	TNF-alpha	Result	
	Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	234	IL-1beta	Result	
	Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	234	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	1 (PreDs)	4	Female	234	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					
	1 (PreDs)	5	Female	238	IFN-gamma	Result	
	Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.					
	1 (PreDs)	5	Female	238	TNF-alpha	Result	
	Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.					
	1 (PreDs)	5	Female	238	IL-1beta	Result	
	Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.					
	1 (PreDs)	5	Female	238	IL-6	Result	
	Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.					
	1 (PreDs)	5	Female	238	IL-10	Result	
	Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.					

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	5	Female	239	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	6	Female	244	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	245	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	245	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	245	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	245	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	245	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	246	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	246	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	246	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	246	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	250	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	250	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	250	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	7	Female	250	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (6 h pa)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Female	244	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	216	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	216	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	1	Female	216	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	221	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	221	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	221	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	222	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	222	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	222	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	3	Female	227	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	228	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	234	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	234	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	234	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	4	Female	234	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	240	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	6	Female	244	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	6	Female	244	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	6	Female	244	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	6	Female	244	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	245	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	245	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	245	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Female	221	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (6 h pa)	2	Female	222	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	3	Female	228	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Female	232	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Female	233	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Female	234	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	5	Female	239	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	7	Female	252	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	245	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	245	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	245	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10 (48h pa)	6	Female	245	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	232	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	4	Female	232	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	232	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	238	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	238	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	238	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	251	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	222	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	2	Female	222	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	228	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	228	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	3	Female	228	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	232	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	232	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	232	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	232	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	233	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	233	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	233	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	233	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	233	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	234	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	234	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Female	234	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	4	Female	234	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	238	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	239	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	7	Female	251	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	251	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	251	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	251	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	251	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	252	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	252	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	252	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	17 (48h pa)	7	Female	252	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			

TABLE 10-1 Urinalysis - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0385 n	6.94 n	37.00 n
	SD	0.0130	0.42	12.32
	N	10	10	10
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0309	6.55	45.80
	SD	0.0057	0.20	5.62
	N	10	10	10
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0377	6.82	43.72
	SD	0.0109	0.40	13.40
	N	10	10	10
	%Diff	0.7	4.1	-4.5
Group 3: 10 µg/ animal BNT162a1	Mean	1.0355	6.77	38.80
	SD	0.0050	0.23	7.32
	N	10	10	10
	%Diff	0.4	3.4	-15.3
Group 4: 30 µg/ animal BNT162b1	Mean	1.0445**	6.62	30.81**
	SD	0.0081	0.26	6.55
	N	10	10	10
	%Diff	1.3	1.1	-32.7

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0458**	6.62	33.79*
	SD	0.0145	0.32	9.05
	N	10	10	10
	%Diff	1.4	1.1	-26.2
Group 7: 100 µg/ animal BNT162b2	Mean	1.0463**	6.35	31.67**
	SD	0.0122	0.27	9.65
	N	10	10	10
	%Diff	1.5	-3.1	-30.9

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

TABLE 10-1 Urinalysis - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0694 n	6.42 n	19.38 n
	SD	0.0218	0.43	9.47
	N	5	5	5
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0374	6.90	27.59
	SD	0.0054	0.29	8.85
	N	5	5	5
	-		-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0384	6.68	28.00
	SD	0.0065	0.32	5.30
	N	5	5	5
	%Diff	0.1	-3.2	1.5
Group 3: 10 µg/ animal BNT162a1	Mean	1.0424	6.56	29.80
	SD	0.0170	0.27	7.62
	N	5	5	5
	%Diff	0.5	-4.9	8.0
Group 4: 30 µg/ animal BNT162b1	Mean	1.0538	6.56	25.98
	SD	0.0248	0.30	14.86
	N	5	5	5
	%Diff	1.6	-4.9	-5.8

[a] - Anova & Dunnett(Rank)
[a1] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0494	6.74	25.73
	SD	0.0158	0.15	11.11
	N	5	5	5
	%Diff	1.2	-2.3	-6.7
Group 7: 100 µg/ animal BNT162b2	Mean	1.0352	6.74	34.74
	SD	0.0026	0.34	4.99
	N	5	5	5
	%Diff	-0.2	-2.3	25.9

[a] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0377 n	6.46 n	47.65 n
	SD	0.0130	0.33	15.30
	N	10	10	10
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0349	6.26	45.54
	SD	0.0047	0.26	10.71
	N	10	10	10
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0391	6.39	48.55
	SD	0.0177	0.28	21.35
	N	10	10	10
	%Diff	0.4	2.1	6.6
Group 3: 10 µg/ animal BNT162a1	Mean	1.0408	6.27	42.62
	SD	0.0129	0.18	13.71
	N	10	10	10
	%Diff	0.6	0.2	-6.4
Group 4: 30 µg/ animal BNT162b1	Mean	1.0555**	6.15	32.31
	SD	0.0199	0.28	11.72
	N	10	10	10
	%Diff	2.0	-1.8	-29.1

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0464	6.27	38.55
	SD	0.0157	0.21	13.43
	N	10	10	10
	%Diff	1.1	0.2	-15.4
Group 7: 100 µg/ animal BNT162b2	Mean	1.0400	6.26	38.35
	SD	0.0099	0.20	15.62
	N	10	10	10
	%Diff	0.5	0.0	-15.8

[a] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0406 n	6.18 n	30.70 n
	SD	0.0081	0.39	5.74
	N	5	5	5
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0484	6.06	35.81
	SD	0.0316	0.38	19.38
	N	5	5	5
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0504	6.16	27.90
	SD	0.0208	0.53	15.15
	N	5	5	5
	%Diff	0.2	1.7	-22.1
Group 3: 10 µg/ animal BNT162a1	Mean	1.0410	6.24	28.12
	SD	0.0074	0.11	9.35
	N	5	5	5
	%Diff	-0.7	3.0	-21.5
Group 4: 30 µg/ animal BNT162b1	Mean	1.0542	6.26	26.63
	SD	0.0256	0.38	14.99
	N	5	5	5
	%Diff	0.6	3.3	-25.6

[a] - Anova & Dunnett(Rank)
[a1] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0474	6.48	28.22
	SD	0.0174	0.31	17.07
	N	5	5	5
	%Diff	-0.1	6.9	-21.2
Group 7: 100 µg/ animal BNT162b2	Mean	1.0432	6.28	29.37
	SD	0.0151	0.29	6.47
	N	5	5	5
	%Diff	-0.5	3.6	-18.0

[a] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics
	17	4	Male	Specific Gravity	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Urine Volume - relative -	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Specific Gravity	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Urine Volume - relative -	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Specific Gravity	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Urine Volume - relative -	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Female	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics
	17	4	Female	Specific Gravity	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	31	6	Female	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
151	SC	1.032	6.8	6.6	34.7
152	LC	1.052	6.6	5.1	23.2
153	LC	1.058	6.3	3.5	18.7
154	SC	1.025	7.2	9.9	48.2
155	SC	1.029	7.4	10.0	47.4
156	SC	1.034	7.0	7.3	36.8
157	SC	1.027	7.3	12.6	57.2
158	SC	1.042	7.1	6.8	37.4
159	SC	1.028	7.4	8.8	42.2
160	LC	1.058	6.3	4.4	24.0
Mean	-	1.0385	6.94	7.50	37.00
SD	-	0.0130	0.42	2.84	12.32
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
1	SC	1.026	6.6	12.0	51.3
2	SC	1.044	6.5	7.9	34.3
3	SC	1.028	6.4	11.1	44.2
4	SC	1.024	7.0	11.8	48.9
5	SC	1.034	6.6	10.5	44.8
6	SC	1.034	6.3	11.3	44.9
7	SC	1.030	6.6	11.8	49.8
8	SC	1.033	6.4	10.4	42.7
9	SC	1.029	6.7	10.7	42.7
10	SC	1.027	6.4	13.4	54.4
Mean	-	1.0309	6.55	11.09	45.80
SD	-	0.0057	0.20	1.43	5.62
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
31	SC	1.030	6.7	7.5	38.6
32	SC	1.032	7.3	9.4	48.0
33	LC	1.060	6.0	5.2	24.4
34	SC	1.031	7.0	9.2	45.4
35	SC	1.031	7.0	12.2	59.7
36	SC	1.037	6.8	8.1	40.4
37	LC	1.045	7.1	6.5	32.0
38	SC	1.029	7.1	12.9	61.8
39	LC	1.052	6.3	4.9	28.2
40	SC	1.030	6.9	11.5	58.7
Mean	-	1.0377	6.82	8.74	43.72
SD	-	0.0109	0.40	2.82	13.40
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
61	SC	1.032	7.1	9.8	39.0
62	SC	1.032	7.1	9.1	42.0
63	SC	1.038	6.8	9.7	38.9
64	LC	1.039	6.7	8.6	37.0
65	LC	1.038	6.7	7.3	30.8
66	SC	1.030	7.0	10.3	44.5
67	SC	1.028	6.7	11.3	44.3
68	LC	1.045	6.5	4.9	24.8
69	SC	1.036	6.5	11.3	50.6
70	SC	1.037	6.6	8.9	36.1
Mean	-	1.0355	6.77	9.12	38.80
SD	-	0.0050	0.23	1.92	7.32
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
91	LC	1.050	6.4	5.5	25.1
92	LC	1.060	6.5	5.3	25.2
93	LC	1.049	6.5	5.3	24.6
94	SC	1.035	6.6	8.2	38.5
95	LC	1.045	6.6	5.7	26.2
96	SC	1.030	7.3	10.1	43.0
97	SC	1.043	6.7	7.9	36.5
98	SC	1.044	6.4	6.7	31.2
99	LC	1.045	6.6	6.0	26.3
100	SC	1.044	6.6	6.7	31.6
Mean	-	1.0445	6.62	6.74	30.81
SD	-	0.0081	0.26	1.57	6.55
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
121	SC	1.039	6.9	9.0	37.6
122	SC	1.041	6.5	6.9	34.9
123	SC	1.038	7.0	7.2	32.8
124	SC	1.038	6.7	7.7	29.8
125	SC	1.034	6.9	10.2	49.2
126	LC	1.064	6.4	6.5	27.1
127	SC	1.035	6.6	7.8	37.2
128	SC	1.063	6.2	5.0	25.7
129	LC	1.072	6.1	4.0	18.8
130	SC	1.034	6.9	9.5	44.8
Mean	-	1.0458	6.62	7.38	33.79
SD	-	0.0145	0.32	1.93	9.05
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
181	LC	1.048	6.1	4.7	19.9
182	LC	1.049	6.2	5.5	28.0
183	LC	1.070	6.0	4.0	18.7
184	LC	1.054	6.4	5.4	26.3
185	SC	1.035	6.6	9.3	40.0
186	LC	1.060	6.2	6.4	33.0
187	SC	1.037	6.4	8.0	37.6
188	LC	1.041	6.2	5.1	24.1
189	SC	1.036	6.5	9.2	44.7
190	SC	1.033	6.9	9.5	44.2
Mean	-	1.0463	6.35	6.71	31.67
SD	-	0.0122	0.27	2.10	9.65
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
161	LC	1.082	6.1	3.1	11.2
162	LC	1.092	6.1	3.6	14.9
163	LC	1.064	7.1	5.9	20.6
164	SC	1.035	6.6	9.1	35.2
165	LC	1.074	6.2	4.3	14.9
Mean	-	1.0694	6.42	5.20	19.38
SD	-	0.0218	0.43	2.42	9.47
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
11	SC	1.045	6.8	6.1	21.5
12	SC	1.035	6.7	9.3	32.3
13	SC	1.034	6.9	10.0	33.9
14	SC	1.032	7.4	9.5	35.2
15	SC	1.041	6.7	4.5	15.1
Mean	-	1.0374	6.90	7.88	27.59
SD	-	0.0054	0.29	2.44	8.85
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
41	SC	1.037	6.3	7.0	26.7
42	SC	1.047	6.6	5.5	20.6
43	SC	1.034	7.1	10.6	34.5
44	SC	1.031	6.9	7.3	26.6
45	SC	1.043	6.5	8.9	31.6
Mean	-	1.0384	6.68	7.86	28.00
SD	-	0.0065	0.32	1.95	5.30
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
71	SC	1.025	6.6	12.0	40.2
72	SC	1.070	6.5	5.6	20.7
73	SC	1.045	6.4	6.5	24.3
74	SC	1.036	7.0	10.2	32.8
75	SC	1.036	6.3	10.0	31.0
Mean	-	1.0424	6.56	8.86	29.80
SD	-	0.0170	0.27	2.70	7.62
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
101	SC	1.032	6.8	12.4	47.5
102	SC	1.045	6.7	4.5	16.7
103	SC	1.034	6.8	11.4	34.2
104	SC	1.068	6.4	6.1	21.3
105	LC	1.090	6.1	3.0	10.3
Mean	-	1.0538	6.56	7.48	25.98
SD	-	0.0248	0.30	4.20	14.86
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
131	SC	1.037	6.8	7.5	24.4
132	SC	1.060	6.9	5.5	20.2
133	SC	1.062	6.7	6.2	23.7
134	SC	1.028	6.8	13.0	44.6
135	LC	1.060	6.5	4.3	15.7
Mean	-	1.0494	6.74	7.30	25.73
SD	-	0.0158	0.15	3.39	11.11
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
191	SC	1.032	7.2	11.0	40.9
192	SC	1.039	6.9	7.7	27.0
193	SC	1.036	6.3	10.5	35.4
194	SC	1.035	6.7	9.0	36.0
195	SC	1.034	6.6	10.0	34.4
Mean	-	1.0352	6.74	9.64	34.74
SD	-	0.0026	0.34	1.31	4.99
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
151	0	0	+++	0	0	0
152	0	0	+++	0	0	0
153	+	0	+++	0	0	0
154	0	0	+++	0	0	0
155	0	0	+++	0	0	0
156	0	0	+++	0	0	0
157	0	0	+++	0	0	0
158	0	0	+++	0	0	0
159	0	0	+++	0	0	0
160	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
1	0	0	++	0	0	0
2	0	+	+++	0	0	0
3	0	0	0	0	0	0
4	+	0	+	0	0	0
5	0	0	0	0	0	0
6	0	0	+	0	0	0
7	0	0	+	0	0	0
8	+	0	0	0	0	0
9	0	+	0	0	0	0
10	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
31	0	0	++	0	0	0
32	0	0	+++	0	0	0
33	0	0	0	0	0	0
34	0	+	+++	0	0	0
35	0	0	+++	0	0	0
36	0	0	+++	0	0	0
37	0	0	+++	0	0	0
38	0	0	++	0	0	0
39	0	0	++	0	0	0
40	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
61	0	0	+++	0	0	0
62	0	0	+++	0	0	0
63	0	0	+++	0	0	0
64	0	0	+++	0	0	0
65	0	0	+++	0	0	0
66	0	0	+++	0	0	0
67	0	0	+++	0	0	0
68	0	0	+++	0	0	0
69	0	0	++	0	0	0
70	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
91	0	0	+++	0	0	0
92	0	0	+++	0	0	0
93	0	0	+++	0	0	0
94	0	0	+	0	0	0
95	0	0	+++	0	0	0
96	0	0	++	0	0	0
97	0	0	+++	0	0	0
98	0	0	++	0	0	0
99	0	0	+++	0	0	0
100	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
121	0	0	+++	0	0	0
122	0	0	++	0	0	0
123	0	0	+++	0	0	0
124	0	0	++	0	0	0
125	0	0	++	0	0	0
126	0	0	+++	0	0	0
127	0	0	++	0	0	0
128	0	0	++	0	0	0
129	0	0	+	0	0	0
130	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
181	0	0	0	0	0	0
182	0	0	0	0	0	0
183	+	0	0	+	0	0
184	+	0	++	0	0	0
185	0	0	+++	0	0	0
186	+	0	++	0	0	0
187	0	0	0	0	0	0
188	0	0	0	0	0	0
189	0	0	++	0	0	0
190	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
161	+	0	0	0	0	0
162	0	0	+++	0	0	0
163	0	0	+++	0	0	0
164	0	0	++	0	0	0
165	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
11	0	0	+++	0	0	0
12	0	0	++	0	0	0
13	0	0	+++	0	0	0
14	0	0	+++	0	0	0
15	+	0	+++	0	0	0

TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
41	0	+	+++	0	0	0
42	0	0	+++	0	0	0
43	0	0	+++	0	0	0
44	0	0	+++	0	0	0
45	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
71	0	0	+	0	0	0
72	0	0	+++	0	0	0
73	0	0	+	0	0	0
74	0	0	+++	0	0	0
75	0	+	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
101	0	0	0	0	0	0
102	+	0	+++	+	0	0
103	0	0	+++	0	0	0
104	0	0	+++	0	0	0
105	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
131	0	0	+++	0	0	0
132	0	0	+++	0	0	0
133	0	0	+++	0	0	0
134	0	0	+++	0	0	0
135	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
191	0	0	++	0	0	0
192	0	+	+++	0	0	0
193	++	0	0	0	0	0
194	0	0	++	0	0	0
195	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
151	pos	0.3	normal	neg	normal	neg	10
152	pos	0.3	normal	neg	normal	neg	10
153	neg	0.3	normal	neg	normal	neg	10
154	pos	0.3	normal	neg	normal	neg	10
155	neg	0.3	normal	neg	normal	neg	neg
156	pos	0.3	normal	neg	normal	neg	10
157	pos	0.3	normal	neg	normal	neg	neg
158	neg	0.3	normal	neg	normal	neg	neg
159	pos	0.3	normal	neg	normal	neg	neg
160	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
1	pos	neg	normal	neg	normal	neg	neg
2	neg	0.3	normal	neg	normal	neg	neg
3	pos	neg	normal	neg	normal	neg	neg
4	pos	0.3	normal	neg	normal	neg	10
5	neg	0.3	normal	neg	normal	neg	10
6	pos	0.3	normal	neg	normal	neg	neg
7	pos	neg	normal	neg	normal	neg	neg
8	pos	neg	normal	neg	normal	neg	neg
9	pos	neg	normal	neg	normal	neg	neg
10	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
31	pos	0.3	normal	neg	normal	neg	10
32	pos	0.3	normal	neg	normal	neg	250
33	neg	0.3	normal	neg	normal	neg	10
34	pos	0.3	normal	neg	normal	neg	10
35	pos	0.3	normal	neg	normal	neg	neg
36	pos	0.3	normal	neg	normal	neg	10
37	pos	0.3	normal	neg	normal	neg	10
38	pos	0.3	normal	neg	normal	neg	neg
39	neg	0.3	normal	neg	normal	neg	neg
40	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
61	pos	0.3	normal	neg	normal	neg	neg
62	pos	0.3	normal	neg	normal	neg	neg
63	neg	0.3	normal	neg	normal	neg	neg
64	neg	0.3	normal	neg	normal	neg	neg
65	neg	0.3	normal	neg	normal	neg	neg
66	pos	0.3	normal	neg	normal	neg	neg
67	pos	neg	normal	neg	normal	neg	neg
68	neg	0.3	normal	neg	normal	neg	neg
69	pos	0.3	normal	neg	normal	neg	neg
70	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
91	pos	0.3	normal	neg	normal	neg	10
92	neg	0.3	normal	neg	normal	neg	neg
93	neg	0.3	normal	neg	normal	neg	25
94	pos	0.3	normal	neg	normal	neg	neg
95	neg	0.3	normal	neg	normal	neg	neg
96	pos	0.3	normal	neg	normal	neg	neg
97	pos	0.3	normal	neg	normal	neg	neg
98	neg	0.3	normal	neg	normal	neg	10
99	neg	0.3	normal	neg	normal	neg	10
100	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
121	pos	0.3	normal	neg	normal	neg	neg
122	pos	0.3	normal	neg	normal	neg	10
123	neg	0.3	normal	neg	normal	neg	neg
124	pos	0.3	normal	neg	normal	neg	neg
125	pos	0.3	normal	neg	normal	neg	neg
126	neg	5.0	normal	neg	normal	neg	10
127	pos	0.3	normal	neg	normal	neg	neg
128	neg	1.0	normal	neg	normal	neg	neg
129	neg	1.0	normal	neg	normal	neg	neg
130	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
181	neg	0.3	normal	neg	normal	neg	neg
182	neg	0.3	normal	neg	normal	neg	neg
183	neg	5.0	normal	neg	normal	neg	10
184	neg	0.3	normal	neg	normal	neg	10
185	pos	0.3	normal	neg	normal	neg	neg
186	neg	1.0	normal	neg	normal	neg	10
187	neg	0.3	normal	neg	normal	neg	neg
188	pos	0.3	normal	neg	normal	neg	10
189	pos	0.3	normal	neg	normal	neg	neg
190	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
161	neg	0.3	normal	neg	normal	neg	neg
162	neg	0.3	normal	neg	normal	neg	10
163	neg	0.3	normal	neg	normal	neg	neg
164	pos	0.3	normal	neg	normal	neg	neg
165	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
11	neg	0.3	normal	neg	normal	neg	neg
12	pos	0.3	normal	neg	normal	neg	neg
13	neg	0.3	normal	neg	normal	neg	neg
14	pos	0.3	normal	neg	normal	neg	neg
15	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
41	pos	0.3	normal	neg	normal	neg	neg
42	pos	0.3	normal	neg	normal	neg	neg
43	pos	0.3	normal	neg	normal	neg	neg
44	neg	0.3	normal	neg	normal	neg	neg
45	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
71	neg	0.3	normal	neg	normal	neg	neg
72	neg	0.3	normal	neg	normal	neg	neg
73	neg	0.3	normal	neg	normal	neg	neg
74	pos	0.3	normal	neg	normal	neg	10
75	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
101	neg	0.3	normal	neg	normal	neg	neg
102	pos	0.3	normal	neg	normal	neg	neg
103	pos	0.3	normal	neg	normal	neg	neg
104	neg	0.3	normal	neg	normal	neg	neg
105	neg	1.0	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
131	pos	1.0	normal	neg	normal	neg	neg
132	neg	0.3	normal	neg	normal	neg	neg
133	neg	0.3	normal	neg	normal	neg	neg
134	pos	0.3	normal	neg	normal	neg	neg
135	neg	0.3	normal	neg	normal	neg	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
191	pos	0.3	normal	neg	normal	neg	neg
192	neg	1.0	normal	neg	normal	neg	neg
193	pos	0.3	normal	neg	normal	neg	neg
194	neg	0.3	normal	neg	normal	neg	neg
195	pos	0.3	normal	neg	normal	neg	neg

TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
166	LC	1.064	6.2	4.9	33.4
167	SC	1.028	6.6	8.2	54.7
168	SC	1.030	6.8	7.8	59.5
169	SC	1.031	6.7	8.1	53.7
170	SC	1.037	6.6	5.5	32.3
171	SC	1.030	6.7	8.2	56.7
172	SC	1.023	6.4	10.3	74.0
173	SC	1.034	6.7	7.3	52.4
174	LC	1.054	5.8	3.8	26.8
175	SC	1.046	6.1	4.9	33.2
Mean	-	1.0377	6.46	6.90	47.65
SD	-	0.0130	0.33	2.03	15.30
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
16	SC	1.032	6.0	10.3	57.3
17	SC	1.031	6.3	6.6	40.9
18	SC	1.031	6.8	8.0	50.9
19	LC	1.042	6.2	5.7	36.1
20	SC	1.032	6.2	9.1	55.4
21	SC	1.038	6.3	7.0	44.0
22	SC	1.036	6.1	6.5	42.2
23	SC	1.039	6.1	4.3	26.6
24	SC	1.040	6.0	6.9	40.5
25	SC	1.028	6.6	10.3	61.7
Mean	-	1.0349	6.26	7.47	45.54
SD	-	0.0047	0.26	1.95	10.71
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
46	SC	1.029	6.4	3.6	23.1
47	SC	1.026	6.9	11.2	72.0
48	SC	1.025	6.3	12.0	71.0
49	LC	1.045	6.5	4.4	29.4
50	SC	1.033	6.4	8.0	51.2
51	SC	1.032	6.5	10.1	71.4
52	SC	1.028	6.7	10.9	70.4
53	LC	1.049	6.2	4.9	33.9
54	SC	1.040	6.0	6.3	42.2
55	LC	1.084	6.0	3.1	20.8
Mean	-	1.0391	6.39	7.45	48.55
SD	-	0.0177	0.28	3.41	21.35
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
76	SC	1.028	6.3	10.2	64.2
77	LC	1.060	6.2	4.7	30.2
78	LC	1.040	6.1	4.7	32.0
79	SC	1.035	6.1	9.8	52.6
80	SC	1.033	6.4	6.3	45.0
81	SC	1.034	6.5	7.5	47.9
82	SC	1.042	6.1	6.4	34.4
83	SC	1.034	6.6	7.2	47.2
84	SC	1.034	6.3	8.4	54.5
85	LC	1.068	6.1	2.8	18.2
Mean	-	1.0408	6.27	6.80	42.62
SD	-	0.0129	0.18	2.33	13.71
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
106	SC	1.043	6.5	6.1	36.0
107	LC	1.096	5.8	2.5	15.1
108	LC	1.046	6.3	5.0	31.7
109	SC	1.034	6.5	10.8	54.6
110	SC	1.039	6.3	6.2	37.2
111	SC	1.041	6.3	7.4	41.8
112	SC	1.068	6.0	4.7	31.2
113	SC	1.046	5.7	6.3	34.8
114	LC	1.070	5.9	3.7	24.0
115	SC	1.072	6.2	2.7	16.8
Mean	-	1.0555	6.15	5.54	32.31
SD	-	0.0199	0.28	2.45	11.72
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
136	SC	1.044	5.9	6.7	38.3
137	LC	1.070	6.1	3.3	21.8
138	LC	1.078	6.2	2.5	17.3
139	SC	1.032	6.4	8.5	52.4
140	SC	1.033	6.5	8.6	58.5
141	SC	1.044	6.4	6.7	40.5
142	SC	1.049	6.1	4.3	28.7
143	SC	1.033	6.3	8.8	52.4
144	SC	1.042	6.2	6.6	39.1
145	SC	1.039	6.6	6.4	36.5
Mean	-	1.0464	6.27	6.24	38.55
SD	-	0.0157	0.21	2.22	13.43
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
196	LC	1.036	6.2	7.5	41.6
197	LC	1.046	6.6	5.4	37.6
198	SC	1.040	6.4	2.7	18.8
199	SC	1.040	6.0	6.0	42.8
200	LC	1.043	6.2	5.9	33.3
201	SC	1.038	6.0	4.4	29.1
202	SC	1.025	6.4	9.6	66.9
203	SC	1.027	6.4	9.6	60.5
204	LC	1.045	6.3	5.6	32.7
205	LC	1.060	6.1	3.1	20.1
Mean	-	1.0400	6.26	5.98	38.35
SD	-	0.0099	0.20	2.37	15.62
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
176	SC	1.054	5.8	3.6	21.5
177	SC	1.039	6.2	5.1	28.8
178	LC	1.038	6.2	5.7	35.3
179	SC	1.040	5.9	5.8	33.6
180	SC	1.032	6.8	7.4	34.3
Mean	-	1.0406	6.18	5.52	30.70
SD	-	0.0081	0.39	1.37	5.74
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
26	SC	1.096	5.6	2.5	14.3
27	SC	1.025	6.4	10.2	47.6
28	SC	1.026	6.2	12.5	56.1
29	SC	1.029	6.4	8.5	45.3
30	SC	1.066	5.7	3.0	15.8
Mean	-	1.0484	6.06	7.34	35.81
SD	-	0.0316	0.38	4.43	19.38
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
56	LC	1.070	5.5	2.8	15.0
57	LC	1.036	6.4	3.5	19.4
58	SC	1.027	6.9	11.2	53.4
59	SC	1.045	6.1	5.9	29.2
60	SC	1.074	5.9	4.1	22.5
Mean	-	1.0504	6.16	5.50	27.90
SD	-	0.0208	0.53	3.39	15.15
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
86	SC	1.032	6.2	7.6	43.7
87	SC	1.047	6.4	5.5	28.2
88	SC	1.037	6.3	4.5	22.0
89	SC	1.050	6.2	4.8	26.6
90	SC	1.039	6.1	3.4	20.0
Mean	-	1.0410	6.24	5.16	28.12
SD	-	0.0074	0.11	1.56	9.35
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
116	SC	1.032	6.4	8.7	44.7
117	SC	1.043	5.9	4.1	21.7
118	LC	1.090	6.3	2.1	10.3
119	LC	1.072	5.9	3.2	16.5
120	SC	1.034	6.8	7.3	39.9
Mean	-	1.0542	6.26	5.08	26.63
SD	-	0.0256	0.38	2.80	14.99
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
146	SC	1.060	6.2	2.4	13.8
147	SC	1.070	6.1	3.0	16.3
148	SC	1.032	6.6	7.0	38.1
149	SC	1.045	6.8	4.0	19.5
150	SC	1.030	6.7	10.5	53.5
Mean	-	1.0474	6.48	5.38	28.22
SD	-	0.0174	0.31	3.36	17.07
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
206	SC	1.070	5.9	3.5	20.7
207	SC	1.035	6.2	5.5	30.1
208	SC	1.040	6.7	4.0	25.1
209	SC	1.036	6.4	6.4	35.4
210	SC	1.035	6.2	7.0	35.5
Mean	-	1.0432	6.28	5.28	29.37
SD	-	0.0151	0.29	1.51	6.47
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
166	+	0	0	0	0	0
167	0	0	0	0	0	0
168	+	0	0	0	0	0
169	0	0	0	0	0	0
170	0	0	0	0	0	0
171	++	0	0	0	0	0
172	++	0	0	0	0	0
173	+	0	0	0	0	0
174	+	0	0	0	0	0
175	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
16	0	0	0	0	0	0
17	+++	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	+	0	0	0	0	0
21	0	0	0	0	0	0
22	0	0	0	0	0	0
23	0	0	+	0	0	0
24	+++	+	0	0	0	0
25	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
46	+	0	0	0	0	0
47	0	0	0	0	0	0
48	+	0	0	0	0	0
49	0	0	++	0	0	0
50	0	0	0	0	0	0
51	0	0	0	0	0	0
52	0	0	0	0	0	0
53	0	0	0	0	0	0
54	+++	0	0	0	0	0
55	++	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
76	+	0	0	0	0	0
77	+	0	+	+	0	0
78	0	0	0	0	0	0
79	0	0	0	+	0	0
80	++	0	0	0	0	0
81	+	0	++	0	0	0
82	0	0	0	0	0	0
83	+	0	0	0	0	0
84	++	0	0	0	0	0
85	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
106	0	0	0	0	0	0
107	0	0	0	0	0	0
108	0	0	0	0	0	0
109	0	0	0	0	0	0
110	0	0	+	0	0	0
111	+	0	0	0	0	0
112	+++	0	0	0	0	0
113	+	0	0	0	0	0
114	0	0	0	0	0	0
115	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
136	0	0	0	0	0	0
137	0	0	++	0	0	0
138	0	0	+	0	0	0
139	+	0	0	0	0	0
140	++	0	0	0	0	0
141	0	0	+	0	0	0
142	+	0	0	0	0	0
143	++	0	0	0	0	0
144	+++	0	0	0	0	0
145	+	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
196	++	0	0	0	0	0
197	0	0	++	0	0	0
198	++	0	0	0	0	0
199	+	0	0	0	0	0
200	+	0	+	0	0	0
201	+	0	0	0	0	0
202	+	0	0	0	0	0
203	++	0	0	0	0	0
204	++	0	+	0	0	0
205	+	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
176	0	0	0	0	0	0
177	0	0	0	0	0	0
178	0	0	0	0	0	0
179	0	0	0	0	0	0
180	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
26	0	0	+++	0	0	0
27	0	0	0	0	0	0
28	+	0	0	0	0	0
29	+	0	0	0	0	0
30	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
56	0	0	0	0	0	0
57	0	0	++	0	0	0
58	0	0	0	0	0	0
59	0	0	0	0	0	0
60	0	0	0	+	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
86	0	0	0	0	0	0
87	0	0	+++	0	0	0
88	0	0	0	0	0	0
89	0	0	0	0	0	0
90	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
116	0	0	0	+	0	0
117	0	0	0	0	0	0
118	0	0	+	0	0	0
119	0	0	0	+	0	0
120	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
146	0	0	0	+	0	0
147	0	0	0	0	0	0
148	0	0	0	0	0	0
149	0	0	+	+	0	0
150	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
206	0	0	0	0	0	0
207	0	0	0	0	0	0
208	0	0	++	0	0	0
209	0	0	0	0	0	0
210	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
166	neg	0.3	normal	neg	normal	neg	neg
167	pos	0.3	normal	neg	normal	neg	neg
168	pos	0.3	normal	neg	normal	neg	neg
169	pos	0.3	normal	neg	normal	neg	neg
170	pos	0.3	normal	neg	normal	neg	neg
171	pos	0.3	normal	neg	normal	neg	neg
172	pos	0.3	normal	neg	normal	neg	10
173	pos	1.0	normal	neg	normal	neg	neg
174	neg	0.3	normal	neg	normal	neg	neg
175	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
16	pos	neg	normal	neg	normal	neg	neg
17	neg	0.3	normal	neg	normal	neg	10
18	pos	neg	normal	neg	normal	neg	neg
19	neg	0.3	normal	neg	normal	neg	neg
20	pos	neg	normal	neg	normal	neg	neg
21	neg	0.3	normal	neg	normal	neg	neg
22	neg	0.3	normal	neg	normal	neg	neg
23	neg	neg	normal	neg	normal	neg	neg
24	neg	neg	normal	neg	normal	neg	neg
25	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
46	pos	0.3	normal	neg	normal	neg	10
47	pos	neg	normal	neg	normal	neg	10
48	pos	neg	normal	neg	normal	neg	25
49	pos	0.3	normal	neg	normal	neg	25
50	pos	0.3	normal	neg	normal	neg	neg
51	pos	0.3	normal	neg	normal	neg	neg
52	pos	neg	normal	neg	normal	neg	neg
53	neg	0.3	normal	neg	normal	neg	neg
54	pos	0.3	normal	neg	normal	neg	neg
55	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
76	pos	neg	normal	neg	normal	neg	neg
77	neg	0.3	normal	neg	normal	neg	neg
78	neg	0.3	normal	neg	normal	neg	neg
79	pos	neg	normal	neg	normal	neg	neg
80	pos	neg	normal	neg	normal	neg	neg
81	pos	neg	normal	neg	normal	neg	neg
82	neg	0.3	normal	neg	normal	neg	neg
83	pos	neg	normal	neg	normal	neg	neg
84	pos	neg	normal	neg	normal	neg	neg
85	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
106	pos	0.3	normal	neg	normal	neg	neg
107	neg	0.3	normal	neg	normal	neg	neg
108	pos	0.3	normal	neg	normal	neg	neg
109	pos	0.3	normal	neg	normal	neg	neg
110	pos	0.3	normal	neg	normal	neg	neg
111	pos	0.3	normal	neg	normal	neg	neg
112	neg	0.3	normal	neg	normal	neg	25
113	neg	0.3	normal	neg	normal	neg	neg
114	neg	0.3	normal	neg	normal	neg	neg
115	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
136	neg	0.3	normal	neg	normal	neg	neg
137	neg	0.3	normal	neg	normal	neg	10
138	neg	0.3	normal	neg	normal	neg	neg
139	pos	0.3	normal	neg	normal	neg	10
140	pos	0.3	normal	neg	normal	neg	10
141	pos	0.3	normal	neg	normal	neg	neg
142	neg	0.3	normal	neg	normal	neg	neg
143	pos	0.3	normal	neg	normal	neg	neg
144	pos	0.3	normal	neg	normal	neg	neg
145	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
196	pos	0.3	normal	neg	normal	neg	neg
197	pos	0.3	normal	neg	normal	neg	neg
198	pos	0.3	normal	neg	normal	neg	neg
199	pos	0.3	normal	neg	normal	neg	neg
200	pos	0.3	normal	neg	normal	neg	neg
201	pos	0.3	normal	neg	normal	neg	neg
202	pos	0.3	normal	neg	normal	neg	neg
203	pos	0.3	normal	neg	normal	neg	neg
204	pos	0.3	normal	neg	normal	neg	neg
205	neg	0.3	normal	neg	normal	neg	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
176	neg	0.3	normal	neg	normal	neg	neg
177	neg	0.3	normal	neg	normal	neg	neg
178	pos	0.3	normal	neg	normal	neg	10
179	neg	0.3	normal	neg	normal	neg	neg
180	pos	0.3	normal	neg	normal	neg	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
26	neg	1.0	normal	neg	normal	neg	neg
27	neg	neg	normal	neg	normal	neg	neg
28	pos	neg	normal	neg	normal	neg	neg
29	neg	neg	normal	neg	normal	neg	neg
30	neg	1.0	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
56	neg	0.3	normal	neg	normal	neg	neg
57	neg	1.0	normal	neg	normal	neg	neg
58	neg	neg	normal	neg	normal	neg	neg
59	neg	0.3	normal	neg	normal	neg	neg
60	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
86	neg	neg	normal	neg	normal	neg	neg
87	neg	0.3	normal	neg	normal	neg	neg
88	pos	0.3	normal	neg	normal	neg	neg
89	neg	0.3	normal	neg	normal	neg	neg
90	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
116	pos	neg	normal	neg	normal	neg	neg
117	neg	neg	normal	neg	normal	neg	neg
118	neg	1.0	normal	neg	normal	neg	neg
119	neg	neg	normal	neg	normal	neg	neg
120	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
146	neg	0.3	normal	neg	normal	neg	neg
147	neg	0.3	normal	neg	normal	neg	neg
148	pos	neg	normal	neg	normal	neg	neg
149	neg	0.3	normal	neg	normal	neg	neg
150	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
206	neg	0.3	normal	neg	normal	neg	neg
207	pos	0.3	normal	neg	normal	neg	neg
208	neg	0.3	normal	neg	normal	neg	10
209	pos	0.3	normal	neg	normal	neg	neg
210	neg	0.3	normal	neg	normal	neg	neg

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 1: Control							
(1)	MS	0	0	0	0	–	–
(2)	MS	0	0	0	0	–	–
(3)	MS	0	0	0	0	–	–
(4)	MS	0	0	0	0	–	–
(5)	MS	0	0	0	0	–	–
(6)	MS	0	0	0	0	–	–
(7)	MS	0	0	0	0	–	–
(8)	MS	0	0	0	0	–	–
(9)	MS	0	0	0	0	–	–
(10)	MS	0	0	0	0	–	–
(11)	RP	0	0	0	0	0	0
(12)	RP	0	0	0	0	0	0
(13)	RP	0	0	0	0	0	0
(14)	RP	0	0	0	0	0	0
(15)	RP	0	0	0	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.							
(31)	MS	0	0	0	0	–	–
(32)	MS	0	0	0	0	–	–
(33)	MS	0	0	0	0	–	–
(34)	MS	0	0	0	0	–	–
(35)	MS	0	0	0	0	–	–
(36)	MS	0	0	0	0	–	–
(37)	MS	0	0	0	0	–	–
(38)	MS	0	0	0	0	–	–
(39)	MS	0	0	0	0	–	–
(40)	MS	0	0	0	0	–	–
(41)	RP	0	0	0	0	0	0
(42)	RP	0	0	0	0	0	0
(43)	RP	0	0	0	0	0	0
(44)	RP	0	0	0	0	0	0
(45)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 3: 10 µg BNT162a1/animal, i.m.							
(61)	MS	0	0	0	0	–	–
(62)	MS	0	0	0	0	–	–
(63)	MS	0	0	0	0	–	–
(64)	MS	0	0	0	0	–	–
(65)	MS	0	0	0	0	–	–
(66)	MS	0	0	0	0	–	–
(67)	MS	0	0	0	0	–	–
(68)	MS	0	0	0	0	–	–
(69)	MS	0	0	0	0	–	–
(70)	MS	0	0	0	0	–	–
(71)	RP	0	0	0	0	0	0
(72)	RP	0	0	0	0	0	0
(73)	RP	0	0	0	0	0	0
(74)	RP	0	0	0	0	0	0
(75)	RP	0	0	0	0	0	0
Group 4: 30 µg BNT162b1/animal, i.m.							
(91)	MS	0	0	0	0	–	–
(92)	MS	0	0	0	0	–	–
(93)	MS	0	0	0	0	–	–
(94)	MS	0	0	0	0	–	–
(95)	MS	0	0	0	0	–	–
(96)	MS	0	0	0	0	–	–
(97)	MS	0	0	0	0	–	–
(98)	MS	0	0	0	0	–	–
(99)	MS	0	0	0	0	–	–
(100)	MS	0	0	0	0	–	–
(101)	RP	0	0	0	0	0	0
(102)	RP	0	0	0	0	0	0
(103)	RP	0	0	0	0	0	0
(104)	RP	0	0	0	0	0	0
(105)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 5: 100 µg BNT162b1/animal, i.m.							
(121)	MS	0	0	0	0	–	–
(122)	MS	0	0	0	0	–	–
(123)	MS	0	0	0	0	–	–
(124)	MS	0	0	0	0	–	–
(125)	MS	0	0	0	0	–	–
(126)	MS	0	0	0	0	–	–
(127)	MS	0	0	0	0	–	–
(128)	MS	0	0	0	0	–	–
(129)	MS	0	0	0	0	–	–
(130)	MS	0	0	0	0	–	–
(131)	RP	0	0	0	0	0	0
(132)	RP	0	0	0	0	0	0
(133)	RP	0	0	0	0	0	0
(134)	RP	0	0	0	0	0	0
(135)	RP	0	0	0	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.							
(151)	MS	0	0	0	0	–	–
(152)	MS	0	0	0	0	–	–
(153)	MS	0	0	0	0	–	–
(154)	MS	0	0	0	0	–	–
(155)	MS	0	0	0	0	–	–
(156)	MS	0	0	0	0	–	–
(157)	MS	0	0	0	0	–	–
(158)	MS	0	0	0	0	–	–
(159)	MS	0	0	0	0	–	–
(160)	MS	0	0	0	0	–	–
(161)	RP	0	0	0	0	0	0
(162)	RP	0	0	0	0	0	0
(163)	RP	0	0	0	0	0	0
(164)	RP	0	0	0	0	0	0
(165)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 7: 100 µg BNT162b2/animal, i.m.							
(181)	MS	0	0	0	0	–	–
(182)	MS	0	0	0	0	–	–
(183)	MS	0	0	0	0	–	–
(184)	MS	0	0	0	0	–	–
(185)	MS	0	0	0	0	–	–
(186)	MS	0	0	0	0	–	–
(187)	MS	0	0	0	0	–	–
(188)	MS	0	0	0	0	–	–
(189)	MS	0	0	0	0	–	–
(190)	MS	0	0	0	0	–	–
(191)	RP	0	0	0	0	0	0
(192)	RP	0	0	0	0	0	0
(193)	RP	0	0	0	0	0	0
(194)	RP	0	0	0	0	0	0
(195)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 1: Control							
(16)	MS	0	0	0	0	–	–
(17)	MS	0	0	0	0	–	–
(18)	MS	0	0	0	0	–	–
(19)	MS	0	0	0	0	–	–
(20)	MS	0	0	0	0	–	–
(21)	MS	0	0	0	0	–	–
(22)	MS	0	0	0	0	–	–
(23)	MS	0	0	0	0	–	–
(24)	MS	0	0	0	0	–	–
(25)	MS	0	0	0	0	–	–
(26)	RP	0	0	0	0	0	0
(27)	RP	0	0	0	0	0	0
(28)	RP	0	0	0	0	0	0
(29)	RP	0	0	0	0	0	0
(30)	RP	0	0	0	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.							
(46)	MS	0	0	0	0	–	–
(47)	MS	0	0	0	0	–	–
(48)	MS	0	0	0	0	–	–
(49)	MS	0	0	0	0	–	–
(50)	MS	0	0	0	0	–	–
(51)	MS	0	0	0	0	–	–
(52)	MS	0	0	0	0	–	–
(53)	MS	0	0	0	0	–	–
(54)	MS	0	0	0	0	–	–
(55)	MS	0	0	0	0	–	–
(56)	RP	0	0	0	0	0	0
(57)	RP	0	0	0	0	0	0
(58)	RP	0	0	0	0	0	0
(59)	RP	0	0	0	0	0	0
(60)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 3: 10 µg BNT162a1/animal, i.m.							
(76)	MS	0	0	0	0	–	–
(77)	MS	0	0	0	0	–	–
(78)	MS	0	0	0	0	–	–
(79)	MS	0	0	0	0	–	–
(80)	MS	0	0	0	0	–	–
(81)	MS	0	0	0	0	–	–
(82)	MS	0	0	0	0	–	–
(83)	MS	0	0	0	0	–	–
(84)	MS	0	0	0	0	–	–
(85)	MS	0	0	0	0	–	–
(86)	RP	0	0	0	0	0	0
(87)	RP	0	0	0	0	0	0
(88)	RP	0	0	0	0	0	0
(89)	RP	0	0	0	0	0	0
(90)	RP	0	0	0	0	0	0
Group 4: 30 µg BNT162b1/animal, i.m.							
(106)	MS	0	0	0	0	–	–
(107)	MS	0	0	0	0	–	–
(108)	MS	0	0	0	0	–	–
(109)	MS	0	0	0	0	–	–
(110)	MS	0	0	0	0	–	–
(111)	MS	0	0	0	0	–	–
(112)	MS	0	0	0	0	–	–
(113)	MS	0	0	0	0	–	–
(114)	MS	0	0	0	0	–	–
(115)	MS	0	0	0	0	–	–
(116)	RP	0	0	0	0	0	0
(117)	RP	0	0	0	0	0	0
(118)	RP	0	0	0	0	0	0
(119)	RP	0	0	0	0	0	0
(120)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 5: 100 µg BNT162b1/animal, i.m.							
(136)	MS	0	0	0	0	–	–
(137)	MS	0	0	0	0	–	–
(138)	MS	0	0	0	0	–	–
(139)	MS	0	0	0	0	–	–
(140)	MS	0	0	0	0	–	–
(141)	MS	0	0	0	0	–	–
(142)	MS	0	0	0	0	–	–
(143)	MS	0	0	0	0	–	–
(144)	MS	0	0	0	0	–	–
(145)	MS	0	0	0	0	–	–
(146)	RP	0	0	0	0	0	0
(147)	RP	0	0	0	0	0	0
(148)	RP	0	0	0	0	0	0
(149)	RP	0	0	0	0	0	0
(150)	RP	0	0	0	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.							
(166)	MS	0	0	0	0	–	–
(167)	MS	0	0	0	0	–	–
(168)	MS	0	0	0	0	–	–
(169)	MS	0	0	0	0	–	–
(170)	MS	0	0	0	0	–	–
(171)	MS	0	0	0	0	–	–
(172)	MS	0	0	0	0	–	–
(173)	MS	0	0	0	0	–	–
(174)	MS	0	0	0	0	–	–
(175)	MS	0	0	0	0	–	–
(176)	RP	0	0	0	0	0	0
(177)	RP	0	0	0	0	0	0
(178)	RP	0	0	0	0	0	0
(179)	RP	0	0	0	0	0	0
(180)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 7: 100 µg BNT162b2/animal, i.m.							
(196)	MS	0	0	0	0	–	–
(197)	MS	0	0	0	0	–	–
(198)	MS	0	0	0	0	–	–
(199)	MS	0	0	0	0	–	–
(200)	MS	0	0	0	0	–	–
(201)	MS	0	0	0	0	–	–
(202)	MS	0	0	0	0	–	–
(203)	MS	0	0	0	0	–	–
(204)	MS	0	0	0	0	–	–
(205)	MS	0	0	0	0	–	–
(206)	RP	0	0	0	0	0	0
(207)	RP	0	0	0	0	0	0
(208)	RP	0	0	0	0	0	0
(209)	RP	0	0	0	0	0	0
(210)	RP	0	0	0	0	0	0

0 = no pathological findings
# = includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins

TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 1: Control				
(1)	MS	0	0	–
(2)	MS	0	0	–
(3)	MS	0	0	–
(4)	MS	0	0	–
(5)	MS	0	0	–
(6)	MS	0	0	–
(7)	MS	0	0	–
(8)	MS	0	0	–
(9)	MS	0	0	–
(10)	MS	0	0	–
(11)	RP	0	0	0
(12)	RP	0	0	0
(13)	RP	0	0	0
(14)	RP	0	0	0
(15)	RP	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.				
(31)	MS	0	0	–
(32)	MS	0	0	–
(33)	MS	0	0	–
(34)	MS	0	0	–
(35)	MS	0	0	–
(36)	MS	0	0	–
(37)	MS	0	0	–
(38)	MS	0	0	–
(39)	MS	0	0	–
(40)	MS	0	0	–
(41)	RP	0	0	0
(42)	RP	0	0	0
(43)	RP	0	0	0
(44)	RP	0	0	0
(45)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 3: 10 µg BNT162a1/animal, i.m.				
(61)	MS	0	0	–
(62)	MS	0	0	–
(63)	MS	0	0	–
(64)	MS	0	0	–
(65)	MS	0	0	–
(66)	MS	0	0	–
(67)	MS	0	0	–
(68)	MS	0	0	–
(69)	MS	0	0	–
(70)	MS	0	0	–
(71)	RP	0	0	0
(72)	RP	0	0	0
(73)	RP	0	0	0
(74)	RP	0	0	0
(75)	RP	0	0	0
Group 4: 30 µg BNT162b1/animal, i.m.				
(91)	MS	0	0	–
(92)	MS	0	0	–
(93)	MS	0	0	–
(94)	MS	0	0	–
(95)	MS	0	0	–
(96)	MS	0	0	–
(97)	MS	0	0	–
(98)	MS	0	0	–
(99)	MS	0	0	–
(100)	MS	0	0	–
(101)	RP	0	0	0
(102)	RP	0	0	0
(103)	RP	0	0	0
(104)	RP	0	0	0
(105)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 5: 100 µg BNT162b1/animal, i.m.				
(121)	MS	0	0	–
(122)	MS	0	0	–
(123)	MS	0	0	–
(124)	MS	0	0	–
(125)	MS	0	0	–
(126)	MS	0	0	–
(127)	MS	0	0	–
(128)	MS	0	0	–
(129)	MS	0	0	–
(130)	MS	0	0	–
(131)	RP	0	0	0
(132)	RP	0	0	0
(133)	RP	0	0	0
(134)	RP	0	0	0
(135)	RP	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.				
(151)	MS	0	0	–
(152)	MS	0	0	–
(153)	MS	0	0	–
(154)	MS	0	0	–
(155)	MS	0	0	–
(156)	MS	0	0	–
(157)	MS	0	0	–
(158)	MS	0	0	–
(159)	MS	0	0	–
(160)	MS	0	0	–
(161)	RP	0	0	0
(162)	RP	0	0	0
(163)	RP	0	0	0
(164)	RP	0	0	0
(165)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 7: 100 µg BNT162b2/animal, i.m.				
(181)	MS	0	0	–
(182)	MS	0	0	–
(183)	MS	0	0	–
(184)	MS	0	0	–
(185)	MS	0	0	–
(186)	MS	0	0	–
(187)	MS	0	0	–
(188)	MS	0	0	–
(189)	MS	0	0	–
(190)	MS	0	0	–
(191)	RP	0	0	0
(192)	RP	0	0	0
(193)	RP	0	0	0
(194)	RP	0	0	0
(195)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 1: Control				
(16)	MS	0	0	–
(17)	MS	0	0	–
(18)	MS	0	0	–
(19)	MS	0	0	–
(20)	MS	0	0	–
(21)	MS	0	0	–
(22)	MS	0	0	–
(23)	MS	0	0	–
(24)	MS	0	0	–
(25)	MS	0	0	–
(26)	RP	0	0	0
(27)	RP	0	0	0
(28)	RP	0	0	0
(29)	RP	0	0	0
(30)	RP	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.				
(46)	MS	0	0	–
(47)	MS	0	0	–
(48)	MS	0	0	–
(49)	MS	0	0	–
(50)	MS	0	0	–
(51)	MS	0	0	–
(52)	MS	0	0	–
(53)	MS	0	0	–
(54)	MS	0	0	–
(55)	MS	0	0	–
(56)	RP	0	0	0
(57)	RP	0	0	0
(58)	RP	0	0	0
(59)	RP	0	0	0
(60)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 3: 10 µg BNT162a1/animal, i.m.				
(76)	MS	0	0	–
(77)	MS	0	0	–
(78)	MS	0	0	–
(79)	MS	0	0	–
(80)	MS	0	0	–
(81)	MS	0	0	–
(82)	MS	0	0	–
(83)	MS	0	0	–
(84)	MS	0	0	–
(85)	MS	0	0	–
(86)	RP	0	0	0
(87)	RP	0	0	0
(88)	RP	0	0	0
(89)	RP	0	0	0
(90)	RP	0	0	0
Group 4: 30 µg BNT162b1/animal, i.m.				
(106)	MS	0	0	–
(107)	MS	0	0	–
(108)	MS	0	0	–
(109)	MS	0	0	–
(110)	MS	0	0	–
(111)	MS	0	0	–
(112)	MS	0	0	–
(113)	MS	0	0	–
(114)	MS	0	0	–
(115)	MS	0	0	–
(116)	RP	0	0	0
(117)	RP	0	0	0
(118)	RP	0	0	0
(119)	RP	0	0	0
(120)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins

TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 5: 100 µg BNT162b1/animal, i.m.				
(136)	MS	0	0	–
(137)	MS	0	0	–
(138)	MS	0	0	–
(139)	MS	0	0	–
(140)	MS	0	0	–
(141)	MS	0	0	–
(142)	MS	0	0	–
(143)	MS	0	0	–
(144)	MS	0	0	–
(145)	MS	0	0	–
(146)	RP	0	0	0
(147)	RP	0	0	0
(148)	RP	0	0	0
(149)	RP	0	0	0
(150)	RP	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.				
(166)	MS	0	0	
(167)	MS	0	0	–
(168)	MS	0	0	–
(169)	MS	0	0	–
(170)	MS	0	0	–
(171)	MS	0	0	–
(172)	MS	0	0	–
(173)	MS	0	0	–
(174)	MS	0	0	–
(175)	MS	0	0	–
(176)	RP	0	0	–
(177)	RP	0	0	0
(178)	RP	0	0	0
(179)	RP	0	0	0
(180)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins

TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 7: 100 µg BNT162b2/animal, i.m.				
(196)	MS	0	0	–
(197)	MS	0	0	–
(198)	MS	0	0	–
(199)	MS	0	0	–
(200)	MS	0	0	–
(201)	MS	0	0	–
(202)	MS	0	0	–
(203)	MS	0	0	–
(204)	MS	0	0	–
(205)	MS	0	0	–
(206)	RP	0	0	0
(207)	RP	0	0	0
(208)	RP	0	0	0
(209)	RP	0	0	0
(210)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 1: Control			
Terminal sacrifice			
(1)	TS / TD 17	—	no pathological findings
(2)	TS / TD 17	—	no pathological findings
(3)	TS / TD 17	—	no pathological findings
(4)	TS / TD 17	—	no pathological findings
(5)	TS / TD 17	—	no pathological findings
(6)	TS / TD 17	—	no pathological findings
(7)	TS / TD 17	Lungs:	emphysematous
(8)	TS / TD 17	—	no pathological findings
(9)	TS / TD 17	Thymus:	reddened
(10)	TS / TD 17	—	no pathological findings
Recovery sacrifice			
(11)	RS / TD 38	—	no pathological findings
(12)	RS / TD 38	—	no pathological findings
(13)	RS / TD 38	—	no pathological findings
(14)	RS / TD 38	—	no pathological findings
(15)	RS / TD 38	Testis (right):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(31)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(32)	TS / TD 17	Injection site I:	indurated
(33)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged
		Prostate:	reduced in size
		Seminal vesicles:	reduced in size
		Adrenal glands:	enlarged
(34)	TS / TD 17	Injection site I:	muscles thickened, indurated
(35)	TS / TD 17	External observation:	injection site I indurated
		Injection site I:	indurated
(36)	TS / TD 17	External observation:	injection site I indurated, incrustation (diameter approx. 4 mm)
		Injection site I:	indurated
(37)	TS / TD 17	External observation:	injection site II incrusted
		Injection site I:	muscles thickened, indurated

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(38)	TS / TD 17	Injection site I:	indurated
(39)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(40)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
Recovery sacrifice			
(41)	RS / TD 38	—	no pathological findings
(42)	RS / TD 38	—	no pathological findings
(43)	RS / TD 38	—	no pathological findings
(44)	RS / TD 38	—	no pathological findings
(45)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(61)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(62)	TS / TD 17	—	no pathological findings
(63)	TS / TD 17	External observation:	injection site I thickened, skin incrusted
		Injection site I:	muscle indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(64)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Lymph node (iliac):	enlarged
(65)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(66)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(67)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscle indurated
(68)	TS / TD 17	Injection site I:	indurated
(69)	TS / TD 17	—	no pathological findings
(70)	TS / TD 17	Spleen:	enlarged
Recovery sacrifice			
(71)	RS / TD 38	—	no pathological findings
(72)	RS / TD 38	—	no pathological findings
(73)	RS / TD 38	—	no pathological findings
(74)	RS / TD 38	—	no pathological findings
(75)	RS / TD 38	—	no pathological findings

TD test day
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 4: 30 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(91)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(92)	TS / TD 17	Injection site I:	indurated
(93)	TS / TD 17	Lymph node (iliac):	enlarged
(94)	TS / TD 17	—	no pathological findings
(95)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(96)	TS / TD 17	Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged
(97)	TS / TD 17	—	no pathological findings
(98)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(99)	TS / TD 17	Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged
(100)	TS / TD 17	Injection site I:	muscle indurated, thickened

TD test day I: left
TS terminal sacrifice II: right

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TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 4: 30 µg BNT162b1/animal, i.m.			
Recovery sacrifice			
(101)	RS / TD 38	—	no pathological findings
(102)	RS / TD 38	—	no pathological findings
(103)	RS / TD 38	Testis (right):	enlarged
(104)	RS / TD 38	—	no pathological findings
(105)	RS / TD 38	—	no pathological findings

TD test day
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(121)	TS / TD 17	Injection site I+II:	enlarged
		Lymph node (renal, left)	enlarged
		Spleen:	enlarged
(122)	TS / TD 17	—	no pathological findings
(123)	TS / TD 17	Injection site I+II:	muscle indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(124)	TS / TD 17	Injection site I+II:	thickened
		Lymph node (iliac):	enlarged
(125)	TS / TD 17	—	no pathological findings
(126)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(127)	TS / TD 17	External observation:	injection site I thickened
		Injection site I+II:	muscle indurated
		Adrenal glands:	enlarged
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(128)	TS / TD 17	Spleen:	enlarged
(129)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
(130)	TS / TD 17	Injection site I+II:	muscle indurated
		Spleen:	enlarged
		Adrenal glands:	enlarged
		Lymph node (iliac):	enlarged
Recovery sacrifice			
(131)	RS / TD 38	Lymph node (iliac):	enlarged
(132)	RS / TD 38	Lymph node (iliac):	enlarged
(133)	RS / TD 38	Lymph node (iliac):	enlarged
(134)	RS / TD 38	Lymph node (iliac):	enlarged
(135)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day I: left
TS terminal sacrifice II: right
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(151)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscles indurated
(152)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Spleen:	enlarged
(153)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
(154)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
		Spleen:	enlarged
(155)	TS / TD 10	Injection site I:	muscle indurated
		Spleen:	enlarged
(156)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(157)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
(158)	TS / TD 10	External observation:	injection site I thickened, incrusted
		Injection site I:	muscle indurated
(159)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
(160)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
		Spleen:	enlarged
Recovery sacrifice			
(161)	RS / TD 31	—	no pathological findings
(162)	RS / TD 31	—	no pathological findings
(163)	RS / TD 31	—	no pathological findings
(164)	RS / TD 31	—	no pathological findings
(165)	RS / TD 31	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 7: 100 µg BNT162b2/animal, i.m.			
Terminal sacrifice			
(181)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
(182)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
(183)	TS / TD 17	—	no pathological findings
(184)	TS / TD 17	External observation:	injection site I thickened
		Injection site I+II:	enlarged
		Lymph node (iliac):	enlarged
		Lymph node (renal):	enlarged
(185)	TS / TD 17	—	no pathological findings
(186)	TS / TD 17	—	no pathological findings
		Injection site I:	indurated
(187)	TS / TD 17	Lymph node (iliac):	enlarged
		Injection site I+II:	indurated
		Spleen:	enlarged
(188)	TS / TD 17	Injection site I+II:	thickened

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 7: 100 µg BNT162b2/animal, i.m.			
(189)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(190)		—	no pathological findings
Recovery sacrifice			
(191)	RS / TD 38	—	no pathological findings
(192)	RS / TD 38	—	no pathological findings
(193)	RS / TD 38	—	no pathological findings
(194)	RS / TD 38	—	no pathological findings
(195)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
RS recovery sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 1: Control			
Terminal sacrifice			
(16)	TS / TD 17	—	no pathological findings
(17)	TS / TD 17	—	no pathological findings
(18)	TS / TD 17	—	no pathological findings
(19)	TS / TD 17	—	no pathological findings
(20)	TS / TD 17	—	no pathological findings
(21)	TS / TD 17	—	no pathological findings
(22)	TS / TD 17	—	no pathological findings
(23)	TS / TD 17	—	no pathological findings
(24)	TS / TD 17	—	no pathological findings
(25)	TS / TD 17	—	no pathological findings
Recovery sacrifice			
(26)	RS / TD 38	—	no pathological findings
(27)	RS / TD 38	—	no pathological findings
(28)	RS / TD 38	—	no pathological findings
(29)	RS / TD 38	—	no pathological findings
(30)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(46)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Spleen:	enlarged
(47)	TS / TD 17	Injection site I:	indurated
(48)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(49)	TS / TD 17	External observation:	injection site I incrusted
		Injection site I:	muscle thickened, indurated
(50)	TS / TD 17	Injection site I:	muscle thickened, indurated
(51)	TS / TD 17	Uterus:	dilated
		Injection site I:	indurated
(52)	TS / TD 17	Injection site I:	muscle thickened, indurated
		Spleen:	enlarged
(53)	TS / TD 17	External observation:	injection site I thickened, skin incrusted
		Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(54)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Spleen:	enlarged
(55)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
Recovery sacrifice			
(56)	RS / TD 38	—	no pathological findings
(57)	RS / TD 38	—	no pathological findings
(58)	RS / TD 38	—	no pathological findings
(59)	RS / TD 38	—	no pathological findings
(60)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(76)	TS / TD 17	—	no pathological findings
(77)	TS / TD 17	—	no pathological findings
(78)	TS / TD 17	Injection site I:	indurated
(79)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
		Uterus:	dilated, filled with clear liquid
		Adrenal glands:	enlarged
(80)	TS / TD 17	Injection site I:	muscle indurated
(81)	TS / TD 17	Injection site I:	indurated
(82)	TS / TD 17	Injection site I:	indurated
		Uterus:	dilated, filled with clear liquid
(83)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
		Uterus:	dilated, filled with clear liquid
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(84)	TS / TD 17	External observation:	injection site I enlarged
		Injection site 1:	enlarged
		Lymph node (iliac):	enlarged
(85)	TS / TD 17	Injection site 1:	thickened
		Lymph node (iliac):	enlarged
Recovery sacrifice			
(86)	RS / TD 38	—	no pathological findings
(87)	RS / TD 38	—	no pathological findings
(88)	RS / TD 38	—	no pathological findings
(89)	RS / TD 38	—	no pathological findings
(90)	RS / TD 38	—	no pathological findings

TD test day
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 4: 30 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(106)	TS / TD 17	Injection site I:	indurated
(107)	TS / TD 17	—	no pathological findings
(108)	TS / TD 17	Injection site I:	muscle indurated, thickened
(109)	TS / TD 17	Uterus:	dilated
		Lymph node (iliac):	enlarged
(110)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(111)	TS / TD 17	Spleen:	enlarged
(112)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(113)	TS / TD 17	Lymph node (iliac):	enlarged
(114)	TS / TD 17	Injection site I:	indurated
(115)	TS / TD 17	Injection site I:	indurated

TD test day I: left
TS terminal sacrifice II: right
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 4: 30 µg BNT162b1/animal, i.m.			
Recovery sacrifice			
(116)	RS / TD 38	Uterus:	dilated, filled with clear liquid
(117)	RS / TD 38	Lymph node (iliac):	enlarged
(118)	RS / TD 38	—	no pathological findings
(119)	RS / TD 38	—	no pathological findings
(120)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(136)	TS / TD 17	Spleen:	enlarged
(137)	TS / TD 17	Injection site I:	muscles indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(138)	TS / TD 17	External observation:	injection site I+II thickened
		Injection site I+II:	muscles indurated
		Lymph node (iliac):	enlarged
(139)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(140)	TS / TD 17	Injection site I+II:	thickened
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(141)	TS / TD 17	Lymph node (iliac):	enlarged
		Spleen:	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(142)	TS / TD 17	Injection site I+II:	thickened
		Sciatic nerve (left):	adhered to injection site I
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(143)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(144)	TS / TD 17	Lymph node (iliac):	enlarged
(145)	TS / TD 17	Spleen:	enlarged
Recovery sacrifice			
(146)	RS / TD 38	—	no pathological findings
(147)	RS / TD 38	Uterus:	dilated, filled with clear liquid
(148)	RS / TD 38	—	no pathological findings
(149)	RS / TD 38	Lymph node (iliac):	enlarged
(150)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(166)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	thickened
(167)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
(168)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Spleen:	enlarged
(169)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
		Lymph node (iliac):	enlarged
(170)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
(171)	TS / TD 10	Injection site I:	muscle indurated
(172)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(173)	TS / TD 10	External observation:	injection site I thickened, incrusted
		Injection site I:	muscle indurated
(174)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Lymph node (iliac):	enlarged
(175)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
Recovery sacrifice			
(176)	RS / TD 31	—	no pathological findings
(177)	RS / TD 31	—	no pathological findings
(178)	RS / TD 31	—	no pathological findings
(179)	RS / TD 31	—	no pathological findings
(180)	RS / TD 31	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 7: 100 µg BNT162b2/animal, i.m.			
Terminal sacrifice			
(196)	TS / TD 17	Injection site I:	thickened
		Spleen:	enlarged
(197)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscle jellied, adhered to sciatic nerve and bone
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(198)	TS / TD 17	Injection site I:	indurated
(199)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Uterus:	dilated, filled with clear liquid
		Lymph node (iliac):	enlarged
(200)	TS / TD 17	Lymph node (iliac):	enlarged
		Injection site I:	indurated
(201)	TS / TD 17	Injection site I+II:	indurated
		Sciatic nerve (left):	adhered to injection site I

TD test day
TS terminal sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 7: 100 µg BNT162b2/animal, i.m.			
Terminal sacrifice			
(202)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(203)	TS / TD 17	Spleen:	enlarged
(204)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(205)	TS / TD 17	Injection site I:	indurated
		Sciatic nerve (left):	adhered to injection site I
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
Recovery sacrifice			
(206)	RS / TD 38	—	no pathological findings
(207)	RS / TD 38	Lymph node (iliac):	enlarged
(208)	RS / TD 38	—	no pathological findings
(209)	RS / TD 38	Lymph node (iliac):	enlarged
(210)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.1473	0.1434	7.245	1.690	1.730	6.458	6.565
	SD	0.0176	0.0158	0.371	0.241	0.280	0.417	0.693
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	4.037	4.984	4.949	40.65	6.285	0.0640	0.1218
	SD	0.589	0.334	0.296	1.58	0.588	0.0122	0.0457
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0371	2.8607	3.775	1.713	0.0405
	SD	0.0032	0.5571	0.508	0.389	0.0115
	N	10	10	10	10	10
	-	-	-	-	-	-

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a1]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a1]	Epididymis (right) (g/kg b.w.) [a1]	Testis (left) (g/kg b.w.) [a1]	Testis (right) (g/kg b.w.) [a]
Group 1: Control	Mean	0.1167	0.1081	6.141	1.401	1.284	5.511	5.447
	SD	0.0144	0.0149	0.207	0.233	0.114	0.448	0.421
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.1529**	0.1498**	7.195**	1.652	1.621**	6.421**	6.472**
	SD	0.0203	0.0235	0.473	0.116	0.176	0.411	0.388
	N	10	10	10	10	10	10	10
	%Diff	31.0	38.6	17.2	17.9	26.2	16.5	18.8
Group 3: 10 µg/ animal BNT162a1	Mean	0.1237	0.1261	6.061	1.759**	1.595**	5.717	5.690
	SD	0.0165	0.0176	0.447	0.256	0.244	0.446	0.348
	N	10	10	10	10	10	10	10
	%Diff	6.0	16.7	-1.3	25.5	24.2	3.7	4.5
Group 4: 30 µg/ animal BNT162b1	Mean	0.1383	0.1299	6.487	1.617	1.525*	5.901	5.840
	SD	0.0165	0.0258	0.304	0.151	0.146	0.369	0.426
	N	10	10	10	10	10	10	10
	%Diff	18.6	20.2	5.6	15.4	18.7	7.1	7.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a]	Epididymis (right) (g/kg b.w.) [a]	Testis (left) (g/kg b.w.) [a]	Testis (right) (g/kg b.w.) [a]
Group 5:	Mean	0.1398	0.1383*	6.432	1.731*	1.754**	5.992	5.867
100 µg/	SD	0.0318	0.0266	0.445	0.193	0.285	0.722	0.587
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	19.8	28.0	4.7	23.6	36.5	8.7	7.7
Group 7:	Mean	0.1439*	0.1248	6.537	1.857**	1.720**	6.180*	6.090**
100 µg/	SD	0.0223	0.0372	0.518	0.359	0.302	0.471	0.367
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	23.4	15.5	6.4	32.5	33.9	12.1	11.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a1]	Kidney (right) (g/kg b.w.) [a1]	Liver (g/kg b.w.) [a1]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a2]
Group 1: Control	Mean	3.493	4.369	4.531	39.90	5.945	0.0644	0.1010
	SD	0.140	0.252	0.325	1.59	1.632	0.0326	0.0487
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.024**	4.819*	4.919	38.93	6.805**	0.0730	0.1428
	SD	0.551	0.481	0.556	3.31	0.799	0.0107	0.0618
	N	10	10	10	10	10	10	10
	%Diff	15.2	10.3	8.6	-2.4	14.5	13.3	41.4
Group 3: 10 µg/ animal BNT162a1	Mean	3.561	4.377	4.459	39.05	6.163	0.0579	0.1204
	SD	0.336	0.315	0.205	2.60	0.548	0.0130	0.0566
	N	10	10	10	10	10	10	10
	%Diff	1.9	0.2	-1.6	-2.1	3.7	-10.1	19.2
Group 4: 30 µg/ animal BNT162b1	Mean	3.623	4.644	4.690	38.73	5.903	0.0740	0.1097
	SD	0.331	0.296	0.275	2.50	0.511	0.0625	0.0620
	N	10	10	10	10	10	10	10
	%Diff	3.7	6.3	3.5	-2.9	-0.7	14.9	8.6

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett: * = $p \leq 0.05$
[a2] - Anova & Dunnett(Log)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	3.771	4.809*	4.745	42.65	6.199	0.0601	0.1463
100 µg/	SD	0.311	0.365	0.296	4.27	0.585	0.0228	0.0788
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	8.0	10.1	4.7	6.9	4.3	-6.7	44.8
Group 7:	Mean	3.799*	4.667	4.810	40.68	6.286	0.0529	0.1687
100 µg/	SD	0.336	0.404	0.442	1.95	0.689	0.0161	0.0948
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	8.8	6.8	6.1	2.0	5.7	-17.8	67.0

[a] - Anova & Dunnett: * = $p \leq 0.05$

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a1]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 1: Control	Mean	0.0391	2.8411	2.568	1.647	0.0402
	SD	0.0043	0.5188	0.378	0.294	0.0095
	N	10	10	10	10	10
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0454	2.9005	3.584**	1.695	0.0509*
	SD	0.0087	0.7572	0.377	0.297	0.0073
	N	10	10	10	10	10
	%Diff	16.0	2.1	39.6	2.9	26.5
Group 3: 10 µg/ animal BNT162a1	Mean	0.0398	2.6968	3.283**	1.618	0.0379
	SD	0.0064	0.6254	0.284	0.369	0.0094
	N	10	10	10	10	10
	%Diff	1.6	-5.1	27.8	-1.8	-5.9
Group 4: 30 µg/ animal BNT162b1	Mean	0.0415	2.7895	3.141**	1.548	0.0443
	SD	0.0066	0.5007	0.332	0.347	0.0071
	N	10	10	10	10	10
	%Diff	6.1	-1.8	22.3	-6.0	10.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank)

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0384	2.5310	3.339**	1.405	0.0338
100 µg/	SD	0.0075	0.6737	0.383	0.264	0.0061
animal	N	10	9	10	10	10
BNT162b1	%Diff	-2.0	-10.9	30.0	-14.7	-16.1
Group 7:	Mean	0.0379	2.7095	3.508**	1.297*	0.0370
100 µg/	SD	0.0043	0.5848	0.268	0.651	0.0113
animal	N	10	10	10	10	10
BNT162b2	%Diff	-3.1	-4.6	36.6	-21.3	-8.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.1009	0.0995	5.544	1.777	1.874	5.170	5.584
	SD	0.0152	0.0138	0.546	0.185	0.156	0.381	1.038
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	3.483	4.223	4.365	35.79	6.070	0.0489	0.1111
	SD	0.365	0.309	0.490	2.13	1.026	0.0141	0.0366
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0349	2.7828	2.242	1.109	0.0399
	SD	0.0050	0.4167	0.258	0.143	0.0113
	N	5	5	5	5	5
	-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a]	Epididymis (right) (g/kg b.w.) [a]	Testis (left) (g/kg b.w.) [a]	Testis (right) (g/kg b.w.) [a1]
Group 1: Control	Mean	0.0979	0.0988	5.356	1.847	1.709	5.426	5.980
	SD	0.0132	0.0144	0.278	0.212	0.160	0.607	1.749
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.1204*	0.1172	5.311	1.803	1.772	5.025	5.139
	SD	0.0116	0.0247	0.232	0.278	0.253	0.284	0.404
	N	5	5	5	5	5	5	4
	%Diff	23.0	18.7	-0.9	-2.4	3.7	-7.4	-14.1
Group 3: 10 µg/ animal BNT162a1	Mean	0.1078	0.1051	5.257	1.977	1.997	5.024	5.021
	SD	0.0080	0.0156	0.221	0.120	0.112	0.390	0.457
	N	5	5	5	5	5	5	5
	%Diff	10.0	6.4	-1.9	7.0	16.9	-7.4	-16.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.0878	0.0874	5.065	1.671	1.547	5.227	5.614
	SD	0.0084	0.0161	0.398	0.256	0.249	0.730	1.635
	N	5	5	5	5	5	5	5
	%Diff	-10.3	-11.5	-5.4	-9.5	-9.4	-3.7	-6.1

[a] - Anova & Dunnett: * = $p \leq 0.05$
[a1] - Anova & Dunnett(Rank)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a]	Epididymis (right) (g/kg b.w.) [a]	Testis (left) (g/kg b.w.) [a]	Testis (right) (g/kg b.w.) [a]
Group 5:	Mean	0.1022	0.1003	5.396	2.090	2.009	5.042	5.077
100 µg/	SD	0.0117	0.0036	0.293	0.217	0.134	0.460	0.500
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	4.3	1.6	0.7	13.2	17.6	-7.1	-15.1
Group 7:	Mean	0.0929	0.0972	5.337	1.882	1.869	5.229	5.235
100 µg/	SD	0.0136	0.0175	0.607	0.218	0.229	0.291	0.423
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	-5.2	-1.5	-0.4	1.9	9.4	-3.6	-12.5

[a] - Anova & Dunnett

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a1]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 1: Control	Mean	3.289	4.378	4.649	35.10	5.281	0.0500	0.0653
	SD	0.138	0.125	0.229	2.91	0.545	0.0145	0.0154
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	3.417	4.246	4.302	36.86	5.639	0.0544	0.0781
	SD	0.163	0.350	0.434	1.85	0.484	0.0389	0.0236
	N	5	5	5	5	5	5	5
	%Diff	3.9	-3.0	-7.5	5.0	6.8	8.8	19.5
Group 3: 10 µg/ animal BNT162a1	Mean	3.414	4.161	4.121	36.34	5.367	0.0550	0.1094
	SD	0.072	0.376	0.097	1.10	0.771	0.0145	0.0212
	N	5	5	5	5	5	5	5
	%Diff	3.8	-5.0	-11.4	3.5	1.6	9.9	67.5
Group 4: 30 µg/ animal BNT162b1	Mean	3.341	4.130	4.186	37.98	5.618	0.0418	0.0693
	SD	0.073	0.226	0.298	1.92	0.169	0.0112	0.0322
	N	5	5	5	5	5	5	5
	%Diff	1.6	-5.7	-10.0	8.2	6.4	-16.5	6.0

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Log)

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	3.364	4.092	4.312	35.73	5.226	0.0464	0.1217*
100 µg/	SD	0.216	0.373	0.462	1.33	0.606	0.0107	0.0290
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	2.3	-6.5	-7.3	1.8	-1.0	-7.3	86.3
Group 7:	Mean	3.486	4.073	4.247	34.46	5.905	0.0469	0.0966
100 µg/	SD	0.306	0.184	0.242	2.39	1.059	0.0071	0.0361
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	6.0	-7.0	-8.7	-1.8	11.8	-6.2	47.8

[a] - Anova & Dunnett: * = $p \leq 0.05$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a1]
Group 1: Control	Mean	0.0323	3.3446	2.112	1.357	0.0389
	SD	0.0027	0.5299	0.176	0.356	0.0189
	N	5	5	5	5	5
	-					
Group 2: 30 µg/ animal BNT162a1	Mean	0.0328	3.3192	2.346	1.273	0.0356
	SD	0.0086	0.6362	0.163	0.385	0.0086
	N	5	5	5	5	5
	%Diff	1.3	-0.8	11.1	-6.2	-8.7
Group 3: 10 µg/ animal BNT162a1	Mean	0.0328	2.8093	2.322	1.148	0.0395
	SD	0.0034	0.6543	0.273	0.192	0.0225
	N	5	5	5	5	5
	%Diff	1.4	-16.0	10.0	-15.4	1.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0339	3.2267	2.191	1.203	0.0377
	SD	0.0048	1.1184	0.132	0.131	0.0154
	N	5	5	5	5	5
	%Diff	4.9	-3.5	3.7	-11.3	-3.0

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0373	3.3528	2.324	1.156	0.0388
100 µg/	SD	0.0025	0.5910	0.177	0.319	0.0078
animal	N	5	5	5	5	5
BNT162b1	%Diff	15.3	0.2	10.0	-14.8	-0.2
Group 7:	Mean	0.0334	2.8265	2.288	1.236	0.0314
100 µg/	SD	0.0032	0.7708	0.339	0.191	0.0021
animal	N	5	5	5	5	5
BNT162b2	%Diff	3.4	-15.5	8.3	-8.9	-19.4

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.2274	0.2123	9.151	0.2262	0.2375	4.003
	SD	0.0316	0.0259	0.564	0.0640	0.0591	0.303
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	4.552	4.757	41.60	7.450	0.0725	0.1139
	SD	0.335	0.446	3.73	0.591	0.0257	0.0464
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0590	3.913	1.821	0.0480
	SD	0.0088	0.627	0.416	0.0101
	N	10	10	10	10
		-	-	-	-

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a1]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a1]	Heart (g/kg b.w.) [a]
Group 1: Control	Mean	0.2049	0.1977	8.438	0.2449	0.2649	4.156
	SD	0.0375	0.0321	0.235	0.0729	0.0490	0.312
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.2231	0.2225	8.840	0.2666	0.2589	4.144
	SD	0.0359	0.0242	0.638	0.0627	0.0906	0.292
	N	10	10	10	10	10	10
	%Diff	8.9	12.5	4.8	8.8	-2.3	-0.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.2093	0.2102	8.551	0.2683	0.2796	3.963
	SD	0.0329	0.0269	0.662	0.0585	0.0438	0.212
	N	10	10	10	10	10	10
	%Diff	2.1	6.3	1.3	9.5	5.5	-4.6
Group 4: 30 µg/ animal BNT162b1	Mean	0.1981	0.1976	8.146	0.2429	0.2321	4.117
	SD	0.0299	0.0274	0.537	0.0314	0.0252	0.295
	N	10	10	10	10	10	10
	%Diff	-3.3	-0.1	-3.5	-0.9	-12.4	-0.9

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a]	Heart (g/kg b.w.) [a]
Group 5:	Mean	0.2241	0.2189	8.128	0.2372	0.2579	3.824
100 µg/	SD	0.0255	0.0248	0.768	0.0367	0.0613	0.389
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	9.4	10.7	-3.7	-3.2	-2.7	-8.0
Group 7:	Mean	0.2280	0.2251	8.598	0.2286	0.2606	3.974
100 µg/	SD	0.0409	0.0326	0.719	0.0593	0.0643	0.260
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	11.3	13.9	1.9	-6.7	-1.6	-4.4

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a1]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a2]
Group 1: Control	Mean	4.255	4.485	37.87	6.054	0.0734	0.1545
	SD	0.293	0.264	2.18	0.486	0.0275	0.0786
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.760**	4.893**	43.81**	7.142**	0.0874	0.1333
	SD	0.279	0.205	2.28	0.782	0.0294	0.0572
	N	10	10	10	10	10	10
	%Diff	11.9	9.1	15.7	18.0	19.2	-13.8
Group 3: 10 µg/ animal BNT162a1	Mean	4.533	4.556	40.61	6.889*	0.0882	0.1801
	SD	0.285	0.207	2.50	0.479	0.0242	0.0424
	N	10	10	10	10	10	10
	%Diff	6.5	1.6	7.2	13.8	20.2	16.5
Group 4: 30 µg/ animal BNT162b1	Mean	4.321	4.448	41.78*	6.777	0.0777	0.1443
	SD	0.207	0.219	3.65	0.599	0.0160	0.1054
	N	10	10	10	10	10	10
	%Diff	1.6	-0.8	10.3	11.9	5.9	-6.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	4.529	4.680	43.65**	6.495	0.0757	0.1840
100 µg/	SD	0.369	0.319	4.48	0.915	0.0254	0.0661
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	6.5	4.3	15.3	7.3	3.2	19.1
Group 7:	Mean	4.635*	4.844**	45.66**	6.972*	0.0785	0.1683
100 µg/	SD	0.389	0.254	2.87	0.473	0.0385	0.1062
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	8.9	8.0	20.6	15.2	6.9	8.9

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a1]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a2]
Group 1: Control	Mean	0.0679	2.701	2.079	0.0587
	SD	0.0086	0.626	0.472	0.0140
	N	10	10	10	10
	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0620	4.523**	2.089	0.0579
	SD	0.0124	0.737	0.480	0.0182
	N	10	10	10	10
	%Diff	-8.8	67.4	0.5	-1.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.0687	3.395	2.243	0.0526
	SD	0.0079	0.251	0.446	0.0143
	N	10	10	10	10
	%Diff	1.1	25.7	7.9	-10.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0606	3.345	1.955	0.0408*
	SD	0.0122	0.385	0.471	0.0054
	N	10	10	10	10
	%Diff	-10.9	23.8	-5.9	-30.5

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): * = $p \leq 0.05$

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0624	4.035**	1.678	0.0412*
100 µg/	SD	0.0116	0.677	0.327	0.0170
animal	N	10	9	10	10
BNT162b1	%Diff	-8.1	49.4	-19.3	-29.9
Group 7:	Mean	0.0661	4.383**	1.795	0.0507
100 µg/	SD	0.0139	0.496	0.525	0.0190
animal	N	10	10	10	10
BNT162b2	%Diff	-2.7	62.3	-13.6	-13.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.1981	0.1926	7.752	0.2609	0.2623	3.760
	SD	0.0302	0.0175	0.664	0.0508	0.0470	0.187
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	4.163	4.273	35.52	5.596	0.0601	0.1696
	SD	0.178	0.176	1.38	0.336	0.0218	0.0477
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0644	2.349	1.792	0.0437
	SD	0.0163	0.258	0.283	0.0069
	N	5	5	5	5
	-	-	-	-	-

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a]	Heart (g/kg b.w.) [a1]
Group 1: Control	Mean	0.2252	0.2232	7.326	0.2286	0.2651	3.804
	SD	0.0279	0.0281	0.511	0.0372	0.0589	0.302
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.1865	0.1744*	7.351	0.2228	0.2578	3.707
	SD	0.0177	0.0356	0.312	0.0542	0.0836	0.225
	N	5	5	5	5	5	5
	%Diff	-17.2	-21.8	0.4	-2.5	-2.7	-2.5
Group 3: 10 µg/ animal BNT162a1	Mean	0.1739	0.1699*	7.465	0.2307	0.2421	3.758
	SD	0.0236	0.0180	0.470	0.0651	0.0534	0.249
	N	5	5	5	5	5	5
	%Diff	-22.8	-23.9	1.9	0.9	-8.7	-1.2
Group 4: 30 µg/ animal BNT162b1	Mean	0.1844	0.1689*	7.309	0.2429	0.2413	3.743
	SD	0.0212	0.0196	0.148	0.0654	0.0552	0.264
	N	5	5	5	5	5	5
	%Diff	-18.1	-24.3	-0.2	6.2	-9.0	-1.6

[a] - Anova & Dunnett: * = $p \leq 0.05$
[a1] - Anova & Dunnett(Rank)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a]	Heart (g/kg b.w.) [a]
Group 5:	Mean	0.2004	0.1979	7.825	0.2633	0.2790	4.287
100 µg/	SD	0.0162	0.0121	0.453	0.0290	0.0270	0.751
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-11.0	-11.3	6.8	15.2	5.2	12.7
Group 7:	Mean	0.2022	0.2081	7.633	0.2086	0.2195	3.956
100 µg/	SD	0.0400	0.0340	0.315	0.0264	0.0298	0.222
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-10.2	-6.7	4.2	-8.8	-17.2	4.0

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a1]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 1: Control	Mean	4.047	4.280	38.19	5.980	0.0722	0.1331
	SD	0.235	0.363	2.39	0.249	0.0178	0.0632
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.060	4.164	38.07	6.155	0.0706	0.1474
	SD	0.282	0.342	2.48	0.719	0.0269	0.0367
	N	5	5	5	5	5	5
	%Diff	0.3	-2.7	-0.3	2.9	-2.2	10.8
Group 3: 10 µg/ animal BNT162a1	Mean	3.985	4.190	34.02*	5.541	0.0674	0.1313
	SD	0.339	0.415	1.34	0.528	0.0174	0.0519
	N	5	5	5	5	5	5
	%Diff	-1.5	-2.1	-10.9	-7.3	-6.6	-1.3
Group 4: 30 µg/ animal BNT162b1	Mean	4.067	4.204	35.36	5.178	0.0717	0.1804
	SD	0.240	0.147	1.62	0.637	0.0224	0.0488
	N	5	5	5	5	5	5
	%Diff	0.5	-1.8	-7.4	-13.4	-0.8	35.5

[a] - Anova & Dunnett: * = $p \leq 0.05$
[a1] - Anova & Dunnett(Log)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	4.289	4.550	39.31	6.208	0.1057	0.1486
100 µg/	SD	0.536	0.568	2.31	0.451	0.0721	0.0295
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	6.0	6.3	2.9	3.8	46.4	11.6
Group 7:	Mean	4.259	4.525	37.99	5.727	0.0617	0.1383
100 µg/	SD	0.554	0.399	2.52	0.132	0.0262	0.0706
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	5.2	5.7	-0.5	-4.2	-14.6	3.9

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 1: Control	Mean	0.0662	2.706	1.943	0.0598
	SD	0.0078	0.367	0.411	0.0118
	N	5	5	5	5
	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0657	2.507	1.638	0.0577
	SD	0.0065	0.305	0.229	0.0159
	N	5	5	5	5
	%Diff	-0.8	-7.4	-15.7	-3.5
Group 3: 10 µg/ animal BNT162a1	Mean	0.0559	2.403	1.778	0.0471
	SD	0.0071	0.158	0.436	0.0136
	N	5	5	5	5
	%Diff	-15.5	-11.2	-8.5	-21.2
Group 4: 30 µg/ animal BNT162b1	Mean	0.0572	2.280	1.550	0.0495
	SD	0.0110	0.171	0.226	0.0086
	N	5	5	5	5
	%Diff	-13.5	-15.8	-20.2	-17.3

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	0.0616	2.885	1.903	0.0442
	SD	0.0113	0.235	0.248	0.0071
	N	5	5	5	5
	%Diff	-6.8	6.6	-2.0	-26.1
Group 7: 100 µg/ animal BNT162b2	Mean	0.0661	2.749	1.639	0.0433
	SD	0.0101	0.249	0.339	0.0120
	N	5	5	5	5
	%Diff	-0.1	1.6	-15.6	-27.6

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Adren. Gland (left)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Adren. Gland (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Brain	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Epididymis (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Testis (left)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Testis (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Epididymis (left)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Epididymis (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Epididymis (right)	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	5	Male	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Male	Epididymis (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Male	Epididymis (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Adren. Gland (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Epididymis (left)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Epididymis (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Testis (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Testis (right)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Heart	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Kidney (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	2	Male	Lungs	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Male	Kidney (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Heart	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Thyroid/Par. (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Thymus	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Male	Adren. Gland (left)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	5	Male	Lymph node (mesent.)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Kidney (left)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Kidney (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Lungs	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Lungs	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	Liver	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Kidney (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Kidney (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Lungs	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Spleen	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	Thyroid/Par. (left)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	5	Female	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Thyroid/Par. (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Female	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05
	38	3	Female	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05
	38	4	Female	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	3	Female	Liver	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
151	0.161	0.146	7.32	1.95	2.07	7.05	8.16
152	0.132	0.142	6.40	1.85	1.68	6.10	5.90
153	0.159	0.167	7.49	1.95	2.27	6.90	7.01
154	0.145	0.137	7.44	1.70	1.63	7.08	7.12
155	0.138	0.156	7.27	1.49	1.42	6.21	6.17
156	0.166	0.154	7.54	2.00	1.96	6.48	6.07
157	0.152	0.148	6.88	1.45	1.62	5.94	6.14
158	0.171	0.146	7.69	1.38	1.42	6.22	6.55
159	0.136	0.114	7.22	1.71	1.57	6.11	6.07
160	0.114	0.122	7.21	1.42	1.65	6.50	6.46
Mean	0.1473	0.1434	7.245	1.690	1.730	6.458	6.565
SD	0.0176	0.0158	0.371	0.241	0.280	0.417	0.693
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
151	4.17	4.79	4.67	42.1	6.36	0.046	0.138
152	3.79	5.21	5.14	37.9	6.13	0.053	0.086
153	3.83	5.50	5.58	39.5	6.46	0.080	0.171
154	3.94	5.13	4.88	40.5	6.86	0.072	0.112
155	3.72	4.82	5.04	41.5	6.99	0.074	0.092
156	4.18	5.09	4.75	41.8	6.03	0.049	0.102
157	3.61	4.62	4.83	41.5	5.30	0.054	0.101
158	5.61	5.41	5.21	42.7	6.96	0.073	0.049
159	3.61	4.50	4.79	40.4	5.43	0.068	0.182
160	3.90	4.77	4.61	38.6	6.34	0.071	0.185
Mean	4.037	4.984	4.949	40.65	6.285	0.0640	0.1218
SD	0.589	0.334	0.296	1.58	0.588	0.0122	0.0457
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
151	0.042	2.842	3.52	2.45	0.061
152	0.040	3.587	3.59	1.78	0.049
153	0.036	3.153	3.55	1.63	0.024
154	0.040	3.873	4.70	1.59	0.033
155	0.039	2.961	4.40	2.34	0.046
156	0.034	2.649	3.32	1.58	0.045
157	0.034	2.214	3.17	1.25	0.027
158	0.033	2.762	3.74	1.63	0.045
159	0.039	2.333	3.47	1.50	0.043
160	0.035	2.233	4.29	1.38	0.032
Mean	0.0371	2.8607	3.775	1.713	0.0405
SD	0.0032	0.5571	0.508	0.389	0.0115
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
166	0.224	0.234	9.06	0.203	0.219	4.58
167	0.203	0.198	9.27	0.198	0.213	3.97
168	0.240	0.223	10.12	0.280	0.354	3.95
169	0.244	0.229	9.32	0.331	0.311	3.82
170	0.156	0.156	8.13	0.196	0.191	4.44
171	0.234	0.202	9.50	0.104	0.145	3.74
172	0.210	0.216	8.83	0.242	0.242	4.10
173	0.267	0.251	8.95	0.295	0.251	3.98
174	0.245	0.213	9.70	0.208	0.213	3.62
175	0.250	0.201	8.63	0.206	0.235	3.82
Mean	0.2274	0.2123	9.151	0.2262	0.2375	4.003
SD	0.0316	0.0259	0.564	0.0640	0.0591	0.303
N	10	10	10	10	10	10

TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
166	4.42	5.00	45.8	7.65	0.026	0.078
167	4.61	4.91	40.7	7.68	0.059	0.099
168	5.03	5.37	41.2	6.29	0.069	0.137
169	4.94	5.09	43.3	7.43	0.122	0.183
170	4.09	4.00	36.9	6.80	0.089	0.173
171	4.26	4.67	37.4	7.68	0.093	0.088
172	4.42	4.21	43.6	8.15	0.058	0.074
173	5.02	5.24	48.6	7.59	0.076	0.082
174	4.37	4.48	38.9	7.04	0.059	0.165
175	4.36	4.61	39.7	8.19	0.074	0.059
Mean	4.552	4.757	41.60	7.450	0.0725	0.1139
SD	0.335	0.446	3.73	0.591	0.0257	0.0464
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
166	0.062	4.06	2.45	0.031
167	0.055	3.27	1.74	0.040
168	0.051	3.49	1.83	0.051
169	0.076	3.36	1.99	0.061
170	0.058	3.96	1.91	0.040
171	0.062	4.00	0.93	0.057
172	0.047	4.36	1.37	0.053
173	0.055	5.13	2.13	0.060
174	0.069	3.09	1.87	0.048
175	0.054	4.41	2.01	0.039
Mean	0.0590	3.913	1.821	0.0480
SD	0.0088	0.627	0.416	0.0101
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
1	0.108	0.096	6.28	1.85	1.34	5.86	5.90
2	0.130	0.114	6.35	1.46	1.27	6.54	6.25
3	0.131	0.116	6.31	1.64	1.34	5.21	5.15
4	0.105	0.108	5.85	1.20	1.23	5.19	4.80
5	0.110	0.122	6.15	1.16	1.26	5.35	5.41
6	0.111	0.087	6.10	1.17	1.23	5.32	5.44
7	0.110	0.094	6.45	1.42	1.48	5.13	5.19
8	0.146	0.137	5.97	1.58	1.43	5.88	5.76
9	0.115	0.103	6.11	1.20	1.12	5.32	5.41
10	0.100	0.103	5.85	1.33	1.15	5.32	5.17
Mean	0.1167	0.1081	6.141	1.401	1.284	5.511	5.447
SD	0.0144	0.0149	0.207	0.233	0.114	0.448	0.421
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
31	0.148	0.137	7.17	1.63	1.48	6.76	6.54
32	0.178	0.155	7.41	1.78	1.90	6.75	6.71
33	0.183	0.200	6.84	1.63	1.43	6.10	6.24
34	0.160	0.153	6.50	1.70	1.56	6.29	6.39
35	0.129	0.143	6.86	1.75	1.57	6.18	6.14
36	0.146	0.116	7.51	1.64	1.42	6.02	5.87
37	0.143	0.128	7.26	1.36	1.50	6.38	6.67
38	0.124	0.149	7.09	1.70	1.74	6.39	6.63
39	0.173	0.173	8.25	1.65	1.86	7.32	7.28
40	0.144	0.144	7.07	1.66	1.74	6.03	6.25
Mean	0.1529	0.1498	7.195	1.652	1.621	6.421	6.472
SD	0.0203	0.0235	0.473	0.116	0.176	0.411	0.388
N	10	10	10	10	10	10	10

TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
61	0.108	0.120	5.65	1.83	1.71	5.97	6.08
62	0.126	0.139	6.25	1.42	1.39	5.86	5.86
63	0.110	0.113	5.58	2.24	1.98	6.22	6.01
64	0.108	0.121	6.09	1.79	1.82	5.63	5.69
65	0.119	0.107	5.79	1.54	1.40	5.85	5.82
66	0.115	0.100	6.77	1.87	1.75	5.74	5.49
67	0.130	0.127	5.72	1.91	1.77	5.32	5.63
68	0.119	0.133	6.81	1.94	1.51	6.41	6.05
69	0.140	0.147	6.19	1.56	1.40	5.04	5.10
70	0.161	0.155	5.76	1.47	1.21	5.14	5.17
Mean	0.1237	0.1261	6.061	1.759	1.595	5.717	5.690
SD	0.0165	0.0176	0.447	0.256	0.244	0.446	0.348
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
91	0.111	0.091	6.25	1.53	1.33	5.99	5.82
92	0.134	0.121	7.00	1.62	1.55	5.55	5.62
93	0.127	0.110	6.27	1.67	1.53	6.00	5.74
94	0.142	0.149	6.50	1.31	1.42	5.70	5.63
95	0.159	0.159	6.28	1.69	1.36	6.02	5.98
96	0.142	0.124	6.07	1.63	1.63	5.53	5.44
97	0.139	0.109	6.70	1.62	1.62	5.70	5.50
98	0.167	0.177	6.88	1.84	1.74	6.81	6.95
99	0.122	0.122	6.31	1.78	1.69	5.97	5.90
100	0.141	0.138	6.61	1.48	1.38	5.74	5.81
Mean	0.1383	0.1299	6.487	1.617	1.525	5.901	5.840
SD	0.0165	0.0258	0.304	0.151	0.146	0.369	0.426
N	10	10	10	10	10	10	10

TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
121	0.090	0.111	6.36	2.14	1.84	6.45	6.30
122	0.121	0.125	6.98	1.76	1.69	6.03	6.28
123	0.166	0.186	6.45	1.56	1.69	6.91	6.06
124	0.091	0.110	5.99	1.40	1.51	5.00	5.06
125	0.183	0.148	7.01	1.80	2.45	5.84	5.97
126	0.135	0.123	5.63	1.58	1.50	5.13	4.96
127	0.171	0.181	6.19	1.78	1.55	5.63	5.66
128	0.151	0.126	6.92	1.77	1.62	7.28	6.88
129	0.136	0.130	6.45	1.73	1.73	6.01	5.98
130	0.153	0.143	6.34	1.79	1.96	5.65	5.51
Mean	0.1398	0.1383	6.432	1.731	1.754	5.992	5.867
SD	0.0318	0.0266	0.445	0.193	0.285	0.722	0.587
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
181	0.118	0.112	5.92	1.61	1.70	5.98	6.07
182	0.118	0.114	7.03	1.62	1.62	5.86	6.04
183	0.136	0.115	6.61	1.80	1.49	5.94	5.94
184	0.171	0.174	6.66	1.50	1.37	5.88	5.74
185	0.145	0.133	5.66	1.57	1.66	5.89	5.92
186	0.152	0.129	7.41	1.94	1.90	7.26	6.72
187	0.150	0.047	6.55	1.70	1.50	5.92	5.72
188	0.141	0.121	6.18	1.99	1.73	6.41	6.57
189	0.123	0.119	6.86	2.15	1.77	6.72	6.45
190	0.186	0.183	6.48	2.69	2.46	5.95	5.72
Mean	0.1439	0.1248	6.537	1.857	1.720	6.180	6.090
SD	0.0223	0.0372	0.518	0.359	0.302	0.471	0.367
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
1	3.66	4.75	4.97	39.8	5.26	0.064	0.105
2	3.48	4.59	4.88	41.7	6.41	0.059	0.137
3	3.57	4.29	4.35	42.3	5.54	0.068	0.191
4	3.27	4.53	4.89	37.5	4.98	0.039	0.063
5	3.48	4.25	4.38	40.3	5.19	0.145	0.064
6	3.54	4.14	4.23	40.5	5.05	0.027	0.033
7	3.62	4.25	4.12	41.2	10.41	0.044	0.097
8	3.61	4.03	4.15	38.2	5.58	0.084	0.101
9	3.26	4.70	4.73	39.1	5.96	0.050	0.062
10	3.43	4.17	4.61	38.4	5.08	0.065	0.157
Mean	3.493	4.369	4.531	39.90	5.945	0.0644	0.1010
SD	0.140	0.252	0.325	1.59	1.632	0.0326	0.0487
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
31	3.95	4.92	4.88	38.1	6.76	0.085	0.248
32	3.64	5.82	5.89	42.3	7.44	0.074	0.225
33	4.03	5.04	5.20	41.7	7.00	0.073	0.120
34	3.48	4.69	4.65	39.8	6.57	0.060	0.078
35	4.54	4.79	4.54	41.4	6.00	0.061	0.164
36	3.81	4.49	4.60	41.5	6.28	0.064	0.112
37	3.67	4.44	4.58	37.0	7.00	0.066	0.062
38	5.36	5.00	5.11	31.6	8.66	0.074	0.188
39	4.02	5.03	5.67	39.8	6.30	0.080	0.131
40	3.74	4.00	4.07	36.3	6.03	0.092	0.100
Mean	4.024	4.819	4.919	38.93	6.805	0.0730	0.1428
SD	0.551	0.481	0.556	3.31	0.799	0.0107	0.0618
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
61	3.31	4.03	4.25	37.4	5.51	0.054	0.100
62	3.18	4.57	4.70	41.7	6.15	0.053	0.175
63	3.37	4.12	4.44	35.7	5.93	0.038	0.073
64	3.50	4.55	4.67	35.6	5.51	0.062	0.139
65	3.53	4.72	4.45	43.3	5.49	0.059	0.157
66	4.03	4.68	4.59	40.9	6.34	0.078	0.091
67	3.27	4.25	4.65	36.9	6.53	0.059	0.107
68	3.75	4.61	4.25	39.6	6.34	0.076	0.061
69	4.21	4.47	4.50	40.2	6.92	0.061	0.064
70	3.47	3.78	4.09	39.2	6.92	0.040	0.237
Mean	3.561	4.377	4.459	39.05	6.163	0.0579	0.1204
SD	0.336	0.315	0.205	2.60	0.548	0.0130	0.0566
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
91	4.07	4.49	4.56	37.7	6.64	0.075	0.159
92	3.41	4.69	4.86	34.5	5.14	0.045	0.231
93	3.63	4.73	4.23	38.7	6.17	0.053	0.120
94	4.11	4.91	5.22	43.9	6.71	0.031	0.038
95	3.87	4.86	4.79	39.7	5.75	0.040	0.066
96	3.32	4.41	4.50	39.0	5.92	0.248	0.151
97	3.32	4.14	4.81	37.1	5.37	0.060	0.073
98	3.65	5.18	4.83	41.0	5.73	0.059	0.094
99	3.12	4.59	4.43	38.1	5.53	0.059	0.134
100	3.73	4.43	4.67	37.6	6.08	0.070	0.030
Mean	3.623	4.644	4.690	38.73	5.903	0.0740	0.1097
SD	0.331	0.296	0.275	2.50	0.511	0.0625	0.0620
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
121	4.64	4.40	4.46	39.8	5.88	0.057	0.063
122	3.71	5.18	4.81	41.2	7.57	0.029	0.301
123	3.71	4.76	4.69	42.0	6.19	0.033	0.088
124	3.66	4.59	4.81	41.8	6.52	0.052	0.074
125	3.59	4.73	4.66	41.4	5.80	0.076	0.173
126	3.73	4.78	4.78	47.5	6.34	0.100	0.205
127	3.62	5.17	4.64	39.5	5.79	0.086	0.128
128	3.64	4.18	4.29	43.6	6.38	0.072	0.231
129	3.79	4.95	4.88	37.5	5.42	0.050	0.113
130	3.62	5.35	5.41	52.1	6.11	0.046	0.086
Mean	3.771	4.809	4.745	42.65	6.199	0.0601	0.1463
SD	0.311	0.365	0.296	4.27	0.585	0.0228	0.0788
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
181	3.92	4.28	4.46	39.2	5.62	0.043	0.052
182	3.57	4.83	5.12	38.3	6.37	0.063	0.169
183	3.39	4.55	4.82	42.1	6.24	0.041	0.319
184	4.58	4.61	4.68	40.3	5.60	0.061	0.085
185	3.47	4.35	4.21	42.7	6.31	0.068	0.157
186	3.88	5.28	5.43	43.7	6.50	0.084	0.327
187	3.66	4.06	4.22	38.6	7.12	0.050	0.213
188	3.96	4.51	4.71	40.5	5.69	0.029	0.078
189	3.89	5.22	5.42	38.9	5.73	0.051	0.167
190	3.69	4.99	5.02	42.6	7.68	0.040	0.120
Mean	3.799	4.667	4.810	40.68	6.286	0.0529	0.1687
SD	0.336	0.404	0.442	1.95	0.689	0.0161	0.0948
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
1	0.045	2.001	2.20	1.43	0.041
2	0.039	3.359	2.86	1.89	0.059
3	0.045	2.764	2.44	1.94	0.036
4	0.039	3.360	1.89	1.23	0.039
5	0.032	3.067	2.48	1.55	0.048
6	0.036	2.186	2.88	1.71	0.033
7	0.035	2.852	2.96	1.73	0.025
8	0.039	3.604	3.10	1.58	0.033
9	0.038	2.644	2.47	2.14	0.047
10	0.044	2.573	2.39	1.27	0.041
Mean	0.0391	2.8411	2.568	1.647	0.0402
SD	0.0043	0.5188	0.378	0.294	0.0095
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
31	0.041	3.149	4.18	1.59	0.055
32	0.047	2.485	2.87	1.86	0.054
33	0.040	2.447	3.80	2.13	0.047
34	0.043	2.887	3.87	1.56	0.050
35	0.046	4.789	3.75	2.07	0.039
36	0.064	2.621	3.70	1.79	0.045
37	0.055	2.285	3.34	1.17	0.066
38	0.032	2.153	3.16	1.67	0.050
39	0.047	2.919	3.55	1.35	0.055
40	0.041	3.270	3.63	1.74	0.048
Mean	0.0454	2.9005	3.584	1.695	0.0509
SD	0.0087	0.7572	0.377	0.297	0.0073
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
61	0.040	2.172	3.05	1.17	0.031
62	0.030	2.210	2.98	1.85	0.043
63	0.041	3.151	3.43	1.19	0.038
64	0.037	2.465	3.19	1.33	0.037
65	0.033	2.132	2.97	1.87	0.024
66	0.044	3.374	3.34	1.31	0.034
67	0.045	3.109	3.58	1.63	0.059
68	0.050	3.576	2.99	1.80	0.040
69	0.045	3.037	3.67	2.33	0.041
70	0.034	1.741	3.64	1.69	0.031
Mean	0.0398	2.6968	3.283	1.618	0.0379
SD	0.0064	0.6254	0.284	0.369	0.0094
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
91	0.039	2.545	3.29	1.53	0.049
92	0.048	2.359	2.52	1.38	0.048
93	0.033	3.338	3.10	1.77	0.053
94	0.035	2.872	3.35	1.76	0.038
95	0.053	3.038	2.94	2.05	0.033
96	0.048	2.579	3.38	1.66	0.042
97	0.036	2.735	3.15	1.23	0.036
98	0.042	2.599	3.75	1.91	0.042
99	0.044	3.788	2.97	1.25	0.047
100	0.037	2.041	2.95	0.94	0.054
Mean	0.0415	2.7895	3.141	1.548	0.0443
SD	0.0066	0.5007	0.332	0.347	0.0071
N	10	10	10	10	10

TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
121	0.048	2.118	3.68	1.54	0.042
122	0.026	1.988	3.34	1.43	0.033
123	0.036	2.978	3.75	1.56	0.033
124	0.033	2.785	2.80	1.54	0.036
125	0.048	2.445	3.35	1.24	0.041
126	0.041	2.473	3.75	1.17	0.038
127	0.046	3.291	2.73	1.22	0.033
128	0.032	1.290	3.64	1.15	0.025
129	0.037	-	2.99	1.20	0.033
130	0.037	3.411	3.35	1.99	0.023
Mean	0.0384	2.5310	3.339	1.405	0.0338
SD	0.0075	0.6737	0.383	0.264	0.0061
N	10	9	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
181	0.039	2.909	3.49	0.82	0.021
182	0.041	2.446	3.17	1.25	0.048
183	0.044	3.311	3.36	1.02	0.024
184	0.041	2.040	3.59	1.33	0.048
185	0.033	3.525	3.61	1.01	0.030
186	0.038	2.967	3.65	0.87	0.049
187	0.037	2.269	3.19	0.86	0.033
188	0.029	2.468	3.24	3.04	0.026
189	0.041	3.336	3.96	1.33	0.048
190	0.037	1.825	3.82	1.43	0.043
Mean	0.0379	2.7095	3.508	1.297	0.0370
SD	0.0043	0.5848	0.268	0.651	0.0113
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
16	0.253	0.240	8.36	0.232	0.257	3.90
17	0.215	0.220	8.33	0.394	0.330	4.16
18	0.137	0.152	8.54	0.324	0.334	4.42
19	0.166	0.157	8.67	0.125	0.277	4.61
20	0.186	0.217	8.43	0.231	0.262	3.81
21	0.190	0.171	8.61	0.264	0.204	4.26
22	0.256	0.241	8.83	0.198	0.290	4.58
23	0.225	0.188	8.41	0.234	0.285	4.14
24	0.194	0.186	8.10	0.249	0.186	3.92
25	0.226	0.205	8.10	0.200	0.226	3.75
Mean	0.2049	0.1977	8.438	0.2449	0.2649	4.156
SD	0.0375	0.0321	0.235	0.0729	0.0490	0.312
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
46	0.254	0.240	8.31	0.301	0.423	4.04
47	0.176	0.185	8.66	0.213	0.157	4.17
48	0.232	0.204	8.04	0.282	0.132	4.31
49	0.160	0.243	9.61	0.180	0.194	3.78
50	0.267	0.234	8.58	0.239	0.220	3.84
51	0.259	0.243	9.67	0.207	0.228	4.40
52	0.208	0.179	9.13	0.232	0.256	4.54
53	0.201	0.237	9.32	0.322	0.322	4.48
54	0.231	0.236	9.20	0.381	0.318	4.14
55	0.244	0.224	7.88	0.310	0.339	3.72
Mean	0.2231	0.2225	8.840	0.2666	0.2589	4.144
SD	0.0359	0.0242	0.638	0.0627	0.0906	0.292
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
76	0.182	0.182	8.07	0.326	0.271	4.24
77	0.219	0.219	9.04	0.205	0.214	3.73
78	0.191	0.200	8.46	0.235	0.289	3.77
79	0.259	0.251	7.61	0.223	0.211	4.01
80	0.258	0.205	9.53	0.395	0.305	3.89
81	0.244	0.216	8.90	0.295	0.333	4.08
82	0.186	0.170	7.54	0.268	0.340	4.26
83	0.193	0.198	8.97	0.265	0.289	3.66
84	0.187	0.206	8.32	0.210	0.252	4.11
85	0.175	0.255	9.07	0.260	0.293	3.88
Mean	0.2093	0.2102	8.551	0.2683	0.2796	3.963
SD	0.0329	0.0269	0.662	0.0585	0.0438	0.212
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
106	0.180	0.189	7.76	0.210	0.206	4.03
107	0.216	0.216	8.47	0.264	0.207	3.93
108	0.194	0.185	8.36	0.236	0.259	3.79
109	0.168	0.157	7.61	0.180	0.203	4.55
110	0.211	0.241	7.71	0.220	0.220	3.96
111	0.169	0.173	7.37	0.258	0.238	4.15
112	0.270	0.237	8.72	0.280	0.228	4.55
113	0.184	0.179	7.91	0.273	0.228	4.00
114	0.198	0.207	8.62	0.250	0.278	4.43
115	0.191	0.191	8.92	0.259	0.255	3.78
Mean	0.1981	0.1976	8.146	0.2429	0.2321	4.117
SD	0.0299	0.0274	0.537	0.0314	0.0252	0.295
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
136	0.240	0.220	8.31	0.183	0.183	4.24
137	0.250	0.226	8.57	0.301	0.344	3.63
138	0.196	0.212	6.83	0.220	0.200	3.18
139	0.198	0.181	8.20	0.247	0.243	3.79
140	0.229	0.224	8.77	0.238	0.295	4.34
141	0.208	0.224	7.81	0.220	0.204	3.82
142	0.248	0.219	9.62	0.262	0.335	4.37
143	0.197	0.184	7.99	0.184	0.202	3.77
144	0.209	0.230	7.42	0.267	0.320	3.45
145	0.266	0.270	7.76	0.249	0.253	3.65
Mean	0.2241	0.2189	8.128	0.2372	0.2579	3.824
SD	0.0255	0.0248	0.768	0.0367	0.0613	0.389
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
196	0.161	0.201	7.69	0.177	0.233	3.86
197	0.243	0.228	8.94	0.248	0.214	4.27
198	0.199	0.179	8.72	0.314	0.334	4.19
199	0.308	0.282	9.23	0.246	0.395	3.95
200	0.241	0.237	7.60	0.121	0.201	3.38
201	0.237	0.227	9.28	0.218	0.222	4.12
202	0.261	0.266	9.31	0.281	0.276	3.89
203	0.213	0.231	8.49	0.293	0.267	3.82
204	0.188	0.183	7.59	0.192	0.277	4.18
205	0.230	0.216	9.15	0.197	0.188	4.08
Mean	0.2280	0.2251	8.598	0.2286	0.2606	3.974
SD	0.0409	0.0326	0.719	0.0593	0.0643	0.260
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
16	4.80	4.59	41.2	5.92	0.051	0.090
17	4.12	4.71	36.6	5.72	0.142	0.165
18	4.37	4.56	36.3	6.53	0.069	0.240
19	4.06	3.97	41.1	7.10	0.078	0.083
20	3.81	4.04	35.0	6.12	0.044	0.067
21	4.17	4.58	37.0	5.46	0.069	0.134
22	4.68	4.54	40.1	6.27	0.087	0.212
23	4.18	4.73	37.7	5.88	0.064	0.193
24	4.18	4.60	35.8	5.57	0.076	0.291
25	4.18	4.53	37.9	5.97	0.052	0.070
Mean	4.255	4.485	37.87	6.054	0.0734	0.1545
SD	0.293	0.264	2.18	0.486	0.0275	0.0786
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
46	5.03	5.17	44.6	6.90	0.113	0.183
47	4.63	4.82	42.6	7.55	0.097	0.083
48	4.31	4.59	43.6	6.13	0.036	0.245
49	5.14	5.05	41.2	7.08	0.078	0.082
50	4.64	4.74	41.3	7.69	0.066	0.113
51	5.07	5.02	48.6	7.19	0.057	0.088
52	4.88	4.83	43.5	8.59	0.082	0.087
53	4.88	5.19	46.3	5.79	0.106	0.101
54	4.53	4.67	43.8	7.27	0.135	0.183
55	4.49	4.87	42.5	7.21	0.105	0.167
Mean	4.760	4.893	43.81	7.142	0.0874	0.1333
SD	0.279	0.205	2.28	0.782	0.0294	0.0572
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
76	4.38	4.62	43.4	7.56	0.107	0.191
77	4.94	4.66	41.9	7.64	0.135	0.256
78	4.50	4.55	39.6	6.21	0.098	0.220
79	4.66	4.62	40.9	6.28	0.085	0.109
80	4.84	4.79	39.5	6.74	0.095	0.158
81	4.78	4.50	43.1	6.98	0.052	0.141
82	4.42	4.42	40.7	6.87	0.059	0.213
83	4.58	4.15	37.1	6.99	0.077	0.174
84	4.16	4.39	43.5	7.11	0.098	0.159
85	4.06	4.87	36.4	6.52	0.076	0.180
Mean	4.533	4.556	40.61	6.889	0.0882	0.1801
SD	0.285	0.207	2.50	0.479	0.0242	0.0424
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
106	4.54	4.71	41.6	6.17	0.090	0.231
107	4.36	4.41	36.7	6.61	0.073	0.056
108	4.53	4.62	41.6	6.61	0.051	0.139
109	4.21	4.36	45.9	7.12	0.088	0.092
110	3.92	4.05	41.3	5.68	0.099	0.082
111	4.43	4.59	39.1	6.93	0.056	0.048
112	4.46	4.69	44.6	7.54	0.081	0.100
113	4.28	4.28	47.3	7.01	0.086	0.077
114	4.43	4.52	43.4	7.63	0.090	0.372
115	4.05	4.23	36.4	6.46	0.064	0.246
Mean	4.321	4.448	41.78	6.777	0.0777	0.1443
SD	0.207	0.219	3.65	0.599	0.0160	0.1054
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
136	5.01	4.60	47.7	6.97	0.106	0.155
137	4.38	4.62	41.9	6.92	0.071	0.151
138	3.65	3.92	34.9	5.53	0.043	0.133
139	4.32	4.50	38.4	6.97	0.062	0.225
140	4.76	4.76	44.8	6.62	0.086	0.071
141	4.74	5.07	44.0	6.90	0.042	0.187
142	4.61	4.76	44.2	7.14	0.112	0.136
143	4.74	4.78	47.4	5.79	0.088	0.241
144	4.55	4.76	50.0	4.55	0.053	0.267
145	4.52	5.02	43.2	7.56	0.095	0.274
Mean	4.529	4.680	43.65	6.495	0.0757	0.1840
SD	0.369	0.319	4.48	0.915	0.0254	0.0661
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
196	4.31	4.39	44.7	7.24	0.020	0.093
197	4.66	4.86	46.6	7.38	0.034	0.058
198	4.38	4.68	49.3	6.33	0.110	0.169
199	4.67	4.97	44.6	6.77	0.118	0.221
200	4.02	4.70	41.0	6.84	0.044	0.225
201	5.30	4.64	49.7	7.15	0.071	0.099
202	5.17	4.92	44.8	6.99	0.108	0.123
203	4.44	5.20	45.3	7.37	0.116	0.422
204	4.56	4.86	42.2	6.10	0.051	0.183
205	4.83	5.21	48.3	7.56	0.113	0.089
Mean	4.635	4.844	45.66	6.972	0.0785	0.1683
SD	0.389	0.254	2.87	0.473	0.0385	0.1062
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
16	0.064	2.10	1.97	0.047
17	0.069	2.65	2.38	0.059
18	0.059	2.26	3.19	0.044
19	0.065	4.38	1.48	0.069
20	0.080	2.57	1.91	0.049
21	0.060	2.45	2.31	0.051
22	0.077	2.56	2.08	0.092
23	0.069	2.85	1.70	0.064
24	0.080	2.57	1.90	0.059
25	0.057	2.61	1.87	0.052
Mean	0.0679	2.701	2.079	0.0587
SD	0.0086	0.626	0.472	0.0140
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
46	0.070	4.32	2.54	0.056
47	0.042	3.52	2.45	0.032
48	0.064	4.13	1.91	0.054
49	0.053	4.85	2.57	0.058
50	0.066	4.83	1.31	0.080
51	0.067	4.29	2.59	0.036
52	0.053	5.94	2.27	0.077
53	0.065	5.04	1.61	0.050
54	0.087	4.82	1.49	0.087
55	0.053	3.49	2.15	0.048
Mean	0.0620	4.523	2.089	0.0579
SD	0.0124	0.737	0.480	0.0182
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
76	0.070	3.50	2.33	0.051
77	0.070	3.21	2.47	0.037
78	0.068	3.37	2.44	0.064
79	0.061	2.88	1.94	0.053
80	0.074	3.58	2.11	0.074
81	0.056	3.28	2.11	0.042
82	0.075	3.32	2.37	0.039
83	0.058	3.81	1.59	0.053
84	0.079	3.55	3.23	0.037
85	0.076	3.45	1.84	0.076
Mean	0.0687	3.395	2.243	0.0526
SD	0.0079	0.251	0.446	0.0143
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
106	0.069	3.30	2.10	0.043
107	0.065	2.90	2.20	0.039
108	0.046	3.47	1.99	0.046
109	0.054	3.71	2.87	0.046
110	0.086	3.32	1.34	0.039
111	0.056	4.03	2.22	0.036
112	0.071	2.80	1.52	0.043
113	0.057	3.59	2.12	0.029
114	0.047	3.39	1.89	0.042
115	0.055	2.96	1.32	0.045
Mean	0.0606	3.345	1.955	0.0408
SD	0.0122	0.385	0.471	0.0054
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
136	0.069	4.77	2.24	0.029
137	0.080	3.91	1.46	0.080
138	0.047	2.43	1.18	0.031
139	0.066	3.92	1.68	0.053
140	0.062	4.72	1.67	0.024
141	0.058	4.20	1.33	0.029
142	0.073	4.18	1.70	0.049
143	0.061	4.17	2.15	0.031
144	0.041	-	1.72	0.037
145	0.066	4.03	1.66	0.050
Mean	0.0624	4.035	1.678	0.0412
SD	0.0116	0.677	0.327	0.0170
N	10	9	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
196	0.056	4.79	1.53	0.044
197	0.068	4.52	1.60	0.039
198	0.060	4.63	1.79	0.045
199	0.087	3.74	1.64	0.082
200	0.056	3.54	1.41	0.032
201	0.052	4.40	3.03	0.085
202	0.094	4.53	2.17	0.059
203	0.067	3.95	1.95	0.031
204	0.055	4.56	1.75	0.043
205	0.066	5.16	1.08	0.047
Mean	0.0661	4.383	1.795	0.0507
SD	0.0139	0.496	0.525	0.0190
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
161	0.120	0.115	4.99	1.71	1.81	4.70	4.75
162	0.101	0.091	6.43	1.86	1.98	5.67	5.64
163	0.082	0.089	5.28	1.61	1.71	4.95	5.05
164	0.092	0.114	5.60	2.06	2.09	5.40	7.35
165	0.111	0.088	5.41	1.65	1.78	5.13	5.13
Mean	0.1009	0.0995	5.544	1.777	1.874	5.170	5.584
SD	0.0152	0.0138	0.546	0.185	0.156	0.381	1.038
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
161	3.95	4.38	4.78	39.5	6.22	0.043	0.093
162	3.42	4.57	4.57	34.8	4.97	0.037	0.070
163	3.47	3.78	3.55	34.7	6.38	0.066	0.166
164	2.95	4.06	4.29	35.7	5.23	0.037	0.100
165	3.63	4.33	4.64	34.3	7.55	0.062	0.126
Mean	3.483	4.223	4.365	35.79	6.070	0.0489	0.1111
SD	0.365	0.309	0.490	2.13	1.026	0.0141	0.0366
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
161	0.037	3.100	2.27	0.96	0.048
162	0.037	3.303	1.95	0.95	0.034
163	0.041	2.440	2.65	1.20	0.048
164	0.029	2.739	2.14	1.23	0.023
165	0.031	2.331	2.19	1.21	0.046
Mean	0.0349	2.7828	2.242	1.109	0.0399
SD	0.0050	0.4167	0.258	0.143	0.0113
N	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
176	0.217	0.217	7.73	0.299	0.262	3.66
177	0.233	0.199	8.14	0.242	0.305	3.69
178	0.187	0.169	8.06	0.191	0.191	4.09
179	0.154	0.188	8.22	0.321	0.248	3.68
180	0.199	0.189	6.61	0.252	0.304	3.67
Mean	0.1981	0.1926	7.752	0.2609	0.2623	3.760
SD	0.0302	0.0175	0.664	0.0508	0.0470	0.187
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
176	4.12	4.30	35.3	5.92	0.050	0.154
177	3.90	3.98	34.3	5.04	0.055	0.233
178	4.27	4.36	37.8	5.56	0.098	0.205
179	4.15	4.45	35.5	5.78	0.056	0.120
180	4.37	4.27	34.6	5.67	0.042	0.136
Mean	4.163	4.273	35.52	5.596	0.0601	0.1696
SD	0.178	0.176	1.38	0.336	0.0218	0.0477
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
176	0.081	2.76	2.26	0.041
177	0.064	2.08	1.53	0.042
178	0.080	2.27	1.82	0.053
179	0.051	2.23	1.67	0.047
180	0.045	2.41	1.68	0.035
Mean	0.0644	2.349	1.792	0.0437
SD	0.0163	0.258	0.283	0.0069
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
11	0.092	0.105	5.65	1.70	1.62	5.65	5.70
12	0.111	0.116	5.39	1.86	1.75	5.00	4.85
13	0.108	0.106	4.96	2.06	1.82	4.81	4.84
14	0.078	0.084	5.57	2.04	1.87	5.32	5.48
15	0.101	0.084	5.22	1.58	1.48	6.35	9.03
Mean	0.0979	0.0988	5.356	1.847	1.709	5.426	5.980
SD	0.0132	0.0144	0.278	0.212	0.160	0.607	1.749
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
41	0.132	0.146	5.49	2.03	2.11	5.38	5.55
42	0.124	0.124	5.54	1.66	1.71	5.26	5.42
43	0.108	0.094	4.96	1.46	1.46	4.75	4.80
44	0.130	0.132	5.35	1.72	1.64	4.77	-
45	0.108	0.090	5.21	2.14	1.93	4.97	4.79
Mean	0.1204	0.1172	5.311	1.803	1.772	5.025	5.139
SD	0.0116	0.0247	0.232	0.278	0.253	0.284	0.404
N	5	5	5	5	5	5	4

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
71	0.102	0.100	5.23	2.00	1.97	4.48	4.33
72	0.112	0.090	5.52	2.15	1.96	5.07	5.07
73	0.117	0.125	5.42	1.88	1.96	4.99	5.26
74	0.097	0.092	4.98	1.85	1.90	5.00	4.88
75	0.111	0.117	5.13	2.01	2.19	5.58	5.56
Mean	0.1078	0.1051	5.257	1.977	1.997	5.024	5.021
SD	0.0080	0.0156	0.221	0.120	0.112	0.390	0.457
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
101	0.095	0.095	5.50	1.67	1.61	5.39	5.17
102	0.094	0.072	5.41	1.66	1.71	5.06	5.09
103	0.080	0.069	4.74	1.46	1.22	6.40	8.51
104	0.077	0.096	4.60	1.47	1.37	4.60	4.62
105	0.094	0.106	5.08	2.09	1.82	4.68	4.68
Mean	0.0878	0.0874	5.065	1.671	1.547	5.227	5.614
SD	0.0084	0.0161	0.398	0.256	0.249	0.730	1.635
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
131	0.090	0.100	5.08	1.88	1.78	4.87	4.75
132	0.099	0.101	5.74	2.11	2.08	5.02	5.07
133	0.108	0.102	5.64	2.29	2.10	4.39	4.48
134	0.094	0.094	5.39	2.31	2.09	5.32	5.32
135	0.120	0.104	5.13	1.86	1.99	5.61	5.77
Mean	0.1022	0.1003	5.396	2.090	2.009	5.042	5.077
SD	0.0117	0.0036	0.293	0.217	0.134	0.460	0.500
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
191	0.109	0.115	5.63	1.68	1.74	5.24	5.63
192	0.087	0.100	4.81	1.98	2.00	5.37	4.88
193	0.073	0.075	4.75	1.68	1.56	4.75	4.77
194	0.095	0.083	6.21	1.87	1.90	5.52	5.70
195	0.100	0.112	5.29	2.20	2.15	5.26	5.19
Mean	0.0929	0.0972	5.337	1.882	1.869	5.229	5.235
SD	0.0136	0.0175	0.607	0.218	0.229	0.291	0.423
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
11	3.30	4.45	4.84	31.4	5.96	0.058	0.058
12	3.32	4.28	4.46	37.6	4.61	0.067	0.057
13	3.39	4.25	4.49	38.3	4.91	0.054	0.052
14	3.39	4.36	4.95	35.0	5.65	0.042	0.090
15	3.05	4.55	4.50	33.2	5.27	0.030	0.071
Mean	3.289	4.378	4.649	35.10	5.281	0.0500	0.0653
SD	0.138	0.125	0.229	2.91	0.545	0.0145	0.0154
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
41	3.58	4.22	4.51	34.4	6.14	0.051	0.096
42	3.46	4.69	4.89	38.2	5.82	0.121	0.098
43	3.14	3.76	3.88	35.5	5.76	0.026	0.046
44	3.47	4.11	3.87	37.6	5.64	0.048	0.090
45	3.44	4.44	4.36	38.6	4.84	0.026	0.061
Mean	3.417	4.246	4.302	36.86	5.639	0.0544	0.0781
SD	0.163	0.350	0.434	1.85	0.484	0.0389	0.0236
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
71	3.31	4.11	4.02	38.2	5.38	0.039	0.134
72	3.45	3.85	4.25	35.8	4.91	0.042	0.098
73	3.46	3.98	4.20	35.7	4.69	0.055	0.120
74	3.36	4.05	4.08	35.5	5.19	0.071	0.116
75	3.48	4.81	4.07	36.4	6.66	0.068	0.079
Mean	3.414	4.161	4.121	36.34	5.367	0.0550	0.1094
SD	0.072	0.376	0.097	1.10	0.771	0.0145	0.0212
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
101	3.45	4.48	4.48	37.8	5.78	0.036	0.044
102	3.32	4.07	4.26	38.0	5.73	0.035	0.070
103	3.28	4.16	4.16	41.0	5.45	0.058	0.122
104	3.38	3.85	3.69	35.6	5.71	0.031	0.041
105	3.28	4.09	4.34	37.5	5.42	0.049	0.069
Mean	3.341	4.130	4.186	37.98	5.618	0.0418	0.0693
SD	0.073	0.226	0.298	1.92	0.169	0.0112	0.0322
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
131	3.14	3.54	3.56	33.7	4.63	0.040	0.116
132	3.28	3.87	4.16	37.4	5.20	0.045	0.115
133	3.48	4.34	4.62	35.4	4.81	0.055	0.146
134	3.68	4.32	4.65	36.3	5.29	0.032	0.080
135	3.24	4.39	4.57	35.9	6.19	0.058	0.152
Mean	3.364	4.092	4.312	35.73	5.226	0.0464	0.1217
SD	0.216	0.373	0.462	1.33	0.606	0.0107	0.0290
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
191	3.81	4.26	4.54	34.5	7.40	0.056	0.115
192	3.08	4.03	4.21	33.7	5.58	0.049	0.149
193	3.48	3.95	4.14	37.7	5.26	0.037	0.090
194	3.30	3.86	3.92	31.2	4.75	0.045	0.062
195	3.76	4.27	4.42	35.3	6.54	0.049	0.066
Mean	3.486	4.073	4.247	34.46	5.905	0.0469	0.0966
SD	0.306	0.184	0.242	2.39	1.059	0.0071	0.0361
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
11	0.031	3.937	2.12	1.39	0.058
12	0.034	3.879	2.14	1.19	0.026
13	0.034	3.000	2.19	1.37	0.025
14	0.028	3.131	2.29	1.90	0.025
15	0.034	2.776	1.82	0.94	0.062
Mean	0.0323	3.3446	2.112	1.357	0.0389
SD	0.0027	0.5299	0.176	0.356	0.0189
N	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
41	0.039	3.126	2.08	1.13	0.031
42	0.042	4.182	2.50	1.74	0.048
43	0.024	3.357	2.33	0.77	0.041
44	0.034	2.424	2.36	1.56	0.026
45	0.024	3.506	2.46	1.16	0.032
Mean	0.0328	3.3192	2.346	1.273	0.0356
SD	0.0086	0.6362	0.163	0.385	0.0086
N	5	5	5	5	5

TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
71	0.029	3.119	2.70	1.10	0.032
72	0.032	1.729	2.42	1.06	0.027
73	0.038	2.701	1.96	0.90	0.025
74	0.031	3.090	2.20	1.35	0.036
75	0.034	3.408	2.33	1.33	0.079
Mean	0.0328	2.8093	2.322	1.148	0.0395
SD	0.0034	0.6543	0.273	0.192	0.0225
N	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
101	0.036	3.500	2.22	1.14	0.044
102	0.037	4.566	2.19	1.34	0.059
103	0.033	1.668	2.24	1.17	0.038
104	0.026	2.607	2.32	1.03	0.018
105	0.037	3.793	1.97	1.33	0.030
Mean	0.0339	3.2267	2.191	1.203	0.0377
SD	0.0048	1.1184	0.132	0.131	0.0154
N	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
131	0.033	3.013	2.49	0.71	0.040
132	0.040	2.972	2.21	0.93	0.048
133	0.039	4.176	2.38	1.46	0.036
134	0.037	3.777	2.46	1.37	0.027
135	0.037	2.826	2.07	1.30	0.043
Mean	0.0373	3.3528	2.324	1.156	0.0388
SD	0.0025	0.5910	0.177	0.319	0.0078
N	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
191	0.036	2.822	2.35	1.20	0.034
192	0.028	3.757	1.95	1.00	0.028
193	0.034	3.083	1.92	1.36	0.032
194	0.033	2.845	2.52	1.49	0.033
195	0.036	1.625	2.68	1.12	0.031
Mean	0.0334	2.8265	2.288	1.236	0.0314
SD	0.0032	0.7708	0.339	0.191	0.0021
N	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
26	0.272	0.272	7.37	0.218	0.276	4.16
27	0.211	0.221	7.04	0.269	0.352	3.41
28	0.229	0.212	6.70	0.174	0.188	3.59
29	0.214	0.210	7.45	0.258	0.254	4.00
30	0.201	0.201	8.07	0.224	0.256	3.86
Mean	0.2252	0.2232	7.326	0.2286	0.2651	3.804
SD	0.0279	0.0281	0.511	0.0372	0.0589	0.302
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
56	0.193	0.173	7.40	0.310	0.286	3.90
57	0.171	0.130	7.59	0.166	0.179	3.41
58	0.167	0.156	6.89	0.192	0.189	3.95
59	0.210	0.225	7.66	0.217	0.252	3.58
60	0.192	0.188	7.21	0.228	0.385	3.69
Mean	0.1865	0.1744	7.351	0.2228	0.2578	3.707
SD	0.0177	0.0356	0.312	0.0542	0.0836	0.225
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
86	0.185	0.172	7.89	0.185	0.172	3.86
87	0.206	0.190	7.27	0.327	0.316	3.62
88	0.151	0.158	6.76	0.225	0.215	3.49
89	0.150	0.146	7.53	0.255	0.251	4.13
90	0.178	0.183	7.87	0.161	0.257	3.70
Mean	0.1739	0.1699	7.465	0.2307	0.2421	3.758
SD	0.0236	0.0180	0.470	0.0651	0.0534	0.249
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
116	0.206	0.199	7.44	0.230	0.269	3.78
117	0.166	0.174	7.30	0.217	0.268	3.67
118	0.161	0.150	7.10	0.358	0.304	3.37
119	0.205	0.170	7.46	0.205	0.185	4.10
120	0.184	0.152	7.25	0.204	0.180	3.81
Mean	0.1844	0.1689	7.309	0.2429	0.2413	3.743
SD	0.0212	0.0196	0.148	0.0654	0.0552	0.264
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
146	0.188	0.193	8.04	0.281	0.285	3.77
147	0.195	0.199	8.08	0.299	0.295	5.62
148	0.226	0.218	8.31	0.251	0.255	4.07
149	0.187	0.194	7.25	0.223	0.312	3.98
150	0.206	0.186	7.44	0.264	0.248	3.99
Mean	0.2004	0.1979	7.825	0.2633	0.2790	4.287
SD	0.0162	0.0121	0.453	0.0290	0.0270	0.751
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
206	0.237	0.229	7.70	0.212	0.216	4.06
207	0.198	0.202	7.52	0.186	0.238	4.08
208	0.159	0.193	7.88	0.226	0.193	3.56
209	0.249	0.253	7.92	0.178	0.191	4.02
210	0.168	0.164	7.15	0.241	0.260	4.05
Mean	0.2022	0.2081	7.633	0.2086	0.2195	3.956
SD	0.0400	0.0340	0.315	0.0264	0.0298	0.222
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
26	4.28	4.61	42.0	6.30	0.062	0.107
27	4.21	4.65	38.5	6.10	0.098	0.098
28	3.96	4.20	36.2	6.05	0.051	0.062
29	3.68	3.76	36.1	5.74	0.079	0.190
30	4.09	4.17	38.2	5.71	0.071	0.209
Mean	4.047	4.280	38.19	5.980	0.0722	0.1331
SD	0.235	0.363	2.39	0.249	0.0178	0.0632
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
56	3.90	3.90	35.4	6.92	0.113	0.169
57	4.55	4.55	39.0	5.16	0.065	0.183
58	3.95	3.88	41.7	6.78	0.065	0.141
59	3.85	3.96	36.2	5.87	0.038	0.088
60	4.05	4.53	38.1	6.05	0.072	0.156
Mean	4.060	4.164	38.07	6.155	0.0706	0.1474
SD	0.282	0.342	2.48	0.719	0.0269	0.0367
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
86	3.73	3.86	31.9	5.29	0.055	0.126
87	4.38	4.53	35.0	5.52	0.065	0.202
88	3.91	4.12	34.9	4.93	0.081	0.158
89	4.29	4.70	34.8	6.36	0.089	0.105
90	3.61	3.74	33.5	5.61	0.048	0.065
Mean	3.985	4.190	34.02	5.541	0.0674	0.1313
SD	0.339	0.415	1.34	0.528	0.0174	0.0519
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
116	3.86	4.01	34.7	5.26	0.062	0.148
117	3.95	4.26	33.1	4.78	0.039	0.118
118	3.88	4.13	36.6	4.79	0.088	0.190
119	4.33	4.40	35.2	6.26	0.097	0.201
120	4.33	4.21	37.3	4.81	0.072	0.244
Mean	4.067	4.204	35.36	5.178	0.0717	0.1804
SD	0.240	0.147	1.62	0.637	0.0224	0.0488
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
146	3.73	3.94	35.6	5.78	0.235	0.134
147	4.98	5.34	41.4	6.21	0.072	0.151
148	3.99	4.32	38.7	5.80	0.070	0.140
149	4.02	4.24	40.6	6.39	0.079	0.197
150	4.73	4.92	40.3	6.86	0.074	0.120
Mean	4.289	4.550	39.31	6.208	0.1057	0.1486
SD	0.536	0.568	2.31	0.451	0.0721	0.0295
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
206	4.10	4.40	36.4	5.80	0.085	0.216
207	4.32	4.45	38.0	5.70	0.044	0.210
208	3.56	4.27	34.8	5.53	0.042	0.059
209	5.10	5.23	41.1	5.72	0.095	0.104
210	4.20	4.28	39.7	5.88	0.042	0.103
Mean	4.259	4.525	37.99	5.727	0.0617	0.1383
SD	0.554	0.399	2.52	0.132	0.0262	0.0706
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
26	0.066	3.17	2.55	0.062
27	0.062	2.25	2.11	0.047
28	0.065	2.94	1.78	0.048
29	0.079	2.46	1.82	0.071
30	0.059	2.72	1.46	0.071
Mean	0.0662	2.706	1.943	0.0598
SD	0.0078	0.367	0.411	0.0118
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
56	0.072	2.70	1.53	0.076
57	0.061	2.23	1.62	0.049
58	0.058	2.83	1.85	0.051
59	0.065	2.13	1.87	0.072
60	0.072	2.64	1.32	0.040
Mean	0.0657	2.507	1.638	0.0577
SD	0.0065	0.305	0.229	0.0159
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
86	0.046	2.47	1.38	0.046
87	0.065	2.25	2.51	0.061
88	0.060	2.22	1.55	0.035
89	0.057	2.55	1.66	0.032
90	0.052	2.52	1.78	0.061
Mean	0.0559	2.403	1.778	0.0471
SD	0.0071	0.158	0.436	0.0136
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
116	0.055	2.14	1.48	0.047
117	0.039	2.17	1.50	0.036
118	0.062	2.56	1.90	0.055
119	0.062	2.20	1.58	0.054
120	0.068	2.32	1.28	0.056
Mean	0.0572	2.280	1.550	0.0495
SD	0.0110	0.171	0.226	0.0086
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
146	0.050	2.81	1.68	0.046
147	0.072	3.15	1.67	0.040
148	0.074	2.67	1.89	0.053
149	0.050	3.12	2.26	0.047
150	0.062	2.68	2.02	0.035
Mean	0.0616	2.885	1.903	0.0442
SD	0.0113	0.235	0.248	0.0071
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
206	0.055	2.79	1.86	0.051
207	0.081	2.75	1.58	0.061
208	0.071	2.35	1.09	0.034
209	0.062	3.03	1.95	0.033
210	0.061	2.83	1.72	0.038
Mean	0.0661	2.749	1.639	0.0433
SD	0.0101	0.249	0.339	0.0120
N	5	5	5	5

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0399	0.0389	1.962	0.459	0.468	1.750	1.777
	SD	0.0044	0.0047	0.082	0.071	0.068	0.117	0.165
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	1.090	1.351	1.343	11.03	1.702	0.0173	0.0329
	SD	0.117	0.104	0.115	0.78	0.154	0.0030	0.0116
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0101	0.7786	1.024	0.465	0.0110
	SD	0.0013	0.1757	0.150	0.110	0.0032
	N	10	10	10	10	10
		-	-	-	-	-

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a1]	Brain (g) [a1]	Epididymis (left) (g) [a2]	Epididymis (right) (g) [a2]	Testis (left) (g) [a]	Testis (right) (g) [a]
Group 1: Control	Mean	0.0381	0.0353	2.004	0.457	0.419	1.797	1.776
	SD	0.0050	0.0051	0.065	0.073	0.036	0.121	0.113
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0415	0.0408	1.950	0.449	0.439	1.741	1.756
	SD	0.0059	0.0076	0.063	0.041	0.037	0.074	0.091
	N	10	10	10	10	10	10	10
	%Diff	8.9	15.6	-2.7	-1.8	4.8	-3.1	-1.1
Group 3: 10 µg/ animal BNT162a1	Mean	0.0406	0.0413	1.978	0.577**	0.524**	1.870	1.864
	SD	0.0069	0.0064	0.085	0.100	0.099	0.163	0.172
	N	10	10	10	10	10	10	10
	%Diff	6.6	17.0	-1.3	26.3	25.1	4.1	5.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.0418	0.0392	1.961	0.490	0.462	1.785	1.766
	SD	0.0047	0.0071	0.061	0.054	0.053	0.111	0.118
	N	10	10	10	10	10	10	10
	%Diff	9.7	11.0	-2.1	7.2	10.3	-0.7	-0.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Epididymis (left) (g) [a]	Epididymis (right) (g) [a]	Testis (left) (g) [a]	Testis (right) (g) [a]
Group 5:	Mean	0.0427	0.0425	1.977	0.533	0.539**	1.840	1.801
100 µg/	SD	0.0084	0.0078	0.100	0.067	0.080	0.185	0.130
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	12.1	20.4	-1.3	16.6	28.6	2.4	1.4
Group 7:	Mean	0.0430	0.0373	1.944	0.554*	0.514*	1.843	1.818
100 µg/	SD	0.0072	0.0114	0.034	0.109	0.097	0.136	0.143
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	12.9	5.7	-3.0	21.2	22.7	2.6	2.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a1]	Kidney (right) (g) [a1]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a2]
Group 1: Control	Mean	1.140	1.426	1.479	13.02	1.936	0.0209	0.0330
	SD	0.050	0.086	0.110	0.54	0.504	0.0101	0.0163
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	1.096	1.309	1.334	10.58**	1.853	0.0198	0.0387
	SD	0.182	0.140	0.139	1.09	0.270	0.0028	0.0165
	N	10	10	10	10	10	10	10
	%Diff	-3.9	-8.2	-9.8	-18.7	-4.3	-5.3	17.3
Group 3: 10 µg/ animal BNT162a1	Mean	1.164	1.430	1.461	12.78	2.019	0.0188	0.0399
	SD	0.107	0.090	0.120	1.05	0.232	0.0036	0.0200
	N	10	10	10	10	10	10	10
	%Diff	2.1	0.3	-1.2	-1.8	4.3	-10.0	20.9
Group 4: 30 µg/ animal BNT162b1	Mean	1.095	1.404	1.418	11.72**	1.787	0.0230	0.0334
	SD	0.088	0.077	0.066	0.83	0.170	0.0212	0.0188
	N	10	10	10	10	10	10	10
	%Diff	-3.9	-1.5	-4.1	-10.0	-7.7	10.0	1.2

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Log)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5:	Mean	1.167	1.483	1.466	13.18	1.912	0.0187	0.0440
100 µg/	SD	0.168	0.150	0.167	1.86	0.230	0.0076	0.0214
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	2.4	4.0	-0.9	1.2	-1.2	-10.5	33.3
Group 7:	Mean	1.135	1.390	1.431	12.16	1.877	0.0157	0.0494
100 µg/	SD	0.122	0.093	0.085	1.09	0.232	0.0044	0.0259
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-0.4	-2.5	-3.2	-6.6	-3.0	-24.9	49.7

[a] - Anova & Dunnett

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a1]	Thyroid/Par. (left) (g) [a]
Group 1: Control	Mean	0.0128	0.9274	0.838	0.538	0.0131
	SD	0.0016	0.1703	0.124	0.101	0.0028
	N	10	10	10	10	10
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0123	0.7886	0.976	0.463	0.0138
	SD	0.0023	0.2164	0.131	0.099	0.0019
	N	10	10	10	10	10
	%Diff	-3.9	-15.0	16.5	-13.9	5.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.0130	0.8776	1.079**	0.527	0.0124
	SD	0.0020	0.1862	0.149	0.111	0.0034
	N	10	10	10	10	10
	%Diff	1.6	-5.4	28.8	-2.0	-5.3
Group 4: 30 µg/ animal BNT162b1	Mean	0.0126	0.8465	0.951	0.468	0.0134
	SD	0.0023	0.1704	0.109	0.103	0.0022
	N	10	10	10	10	10
	%Diff	-1.6	-8.7	13.5	-13.0	2.3

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	0.0119	0.7897	1.030**	0.435	0.0105
	SD	0.0027	0.2321	0.145	0.096	0.0025
	N	10	9	10	10	10
	%Diff	-7.0	-14.9	22.9	-19.1	-19.8
Group 7: 100 µg/ animal BNT162b2	Mean	0.0113	0.8130	1.049**	0.388**	0.0109
	SD	0.0013	0.2047	0.116	0.201	0.0028
	N	10	10	10	10	10
	%Diff	-11.7	-12.3	25.2	-27.9	-16.8

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0370	0.0364	2.022	0.648	0.684	1.888	2.034
	SD	0.0064	0.0051	0.104	0.042	0.030	0.087	0.312
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	1.280	1.544	1.596	13.12	2.244	0.0182	0.0414
	SD	0.195	0.111	0.187	1.27	0.522	0.0064	0.0161
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0128	1.0128	0.826	0.408	0.0148
	SD	0.0023	0.1061	0.148	0.071	0.0050
	N	5	5	5	5	5
	-	-	-	-	-	-

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Epididymis (left) (g) [a]	Epididymis (right) (g) [a1]	Testis (left) (g) [a1]	Testis (right) (g) [a1]
Group 1: Control	Mean	0.0382	0.0384	2.076	0.716	0.662	2.108	2.332
	SD	0.0067	0.0063	0.070	0.080	0.055	0.282	0.756
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0452*	0.0438	1.996	0.676	0.664	1.888	1.928
	SD	0.0030	0.0075	0.049	0.090	0.070	0.065	0.083
	N	5	5	5	5	5	5	4
	%Diff	18.3	14.1	-3.9	-5.6	0.3	-10.4	-17.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.0434	0.0424	2.118	0.798	0.808*	2.032	2.028
	SD	0.0032	0.0069	0.103	0.073	0.098	0.269	0.261
	N	5	5	5	5	5	5	5
	%Diff	13.6	10.4	2.0	11.5	22.1	-3.6	-13.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.0346	0.0344	1.996	0.660	0.608	2.080	2.258
	SD	0.0030	0.0061	0.134	0.111	0.085	0.457	0.886
	N	5	5	5	5	5	5	5
	%Diff	-9.4	-10.4	-3.9	-7.8	-8.2	-1.3	-3.2

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank): * = p ≤ 0.05

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Epididymis (left) (g) [a]	Epididymis (right) (g) [a]	Testis (left) (g) [a]	Testis (right) (g) [a]
Group 5:	Mean	0.0394	0.0388	2.086	0.808	0.776*	1.954	1.966
100 µg/	SD	0.0032	0.0019	0.101	0.083	0.038	0.227	0.222
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	3.1	1.0	0.5	12.8	17.2	-7.3	-15.7
Group 7:	Mean	0.0348	0.0366	1.998	0.710	0.704	1.966	1.964
100 µg/	SD	0.0041	0.0068	0.090	0.106	0.099	0.106	0.056
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	-8.9	-4.7	-3.8	-0.8	6.3	-6.7	-15.8

[a] - Anova & Dunnett: * = $p \leq 0.05$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a1]	Lymph node (mesent.) (g) [a]
Group 1: Control	Mean	1.276	1.700	1.802	13.64	2.046	0.0194	0.0252
	SD	0.065	0.106	0.050	1.48	0.182	0.0057	0.0050
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	1.284	1.594	1.614	13.88	2.122	0.0200	0.0290
	SD	0.034	0.078	0.101	1.04	0.205	0.0134	0.0074
	N	5	5	5	5	5	5	5
	%Diff	0.6	-6.2	-10.4	1.8	3.7	3.1	15.1
Group 3: 10 µg/ animal BNT162a1	Mean	1.378	1.688	1.662	14.68	2.184	0.0224	0.0440*
	SD	0.107	0.276	0.102	1.33	0.478	0.0071	0.0083
	N	5	5	5	5	5	5	5
	%Diff	8.0	-0.7	-7.8	7.6	6.7	15.5	74.6
Group 4: 30 µg/ animal BNT162b1	Mean	1.320	1.632	1.654	15.06	2.218	0.0168	0.0282
	SD	0.098	0.154	0.172	2.02	0.145	0.0061	0.0160
	N	5	5	5	5	5	5	5
	%Diff	3.4	-4.0	-8.2	10.4	8.4	-13.4	11.9

[a] - Anova & Dunnett: * = $p \leq 0.05$
[a1] - Anova & Dunnett(Log)

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Three LNP-Formulated
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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5:	Mean	1.302	1.580	1.664	13.82	2.020	0.0178	0.0468*
100 µg/	SD	0.107	0.118	0.144	0.69	0.222	0.0034	0.0098
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	2.0	-7.1	-7.7	1.3	-1.3	-8.2	85.7
Group 7:	Mean	1.314	1.536	1.602	13.04	2.226	0.0176	0.0366
100 µg/	SD	0.154	0.143	0.164	1.85	0.413	0.0024	0.0144
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	3.0	-9.6	-11.1	-4.4	8.8	-9.3	45.2

[a] - Anova & Dunnett: * = $p \leq 0.05$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a1]
Group 1: Control	Mean	0.0126	1.2958	0.818	0.522	0.0152
	SD	0.0017	0.1952	0.054	0.112	0.0077
	N	5	5	5	5	5
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0122	1.2478	0.884	0.474	0.0134
	SD	0.0026	0.2328	0.087	0.128	0.0034
	N	5	5	5	5	5
	%Diff	-3.2	-3.7	8.1	-9.2	-11.8
Group 3: 10 µg/ animal BNT162a1	Mean	0.0132	1.1472	0.940	0.468	0.0164
	SD	0.0013	0.3332	0.147	0.111	0.0107
	N	5	5	5	5	5
	%Diff	4.8	-11.5	14.9	-10.3	7.9
Group 4: 30 µg/ animal BNT162b1	Mean	0.0134	1.2532	0.866	0.476	0.0148
	SD	0.0021	0.3862	0.090	0.067	0.0056
	N	5	5	5	5	5
	%Diff	6.3	-3.3	5.9	-8.8	-2.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5:	Mean	0.0144	1.2952	0.902	0.444	0.0150
100 µg/	SD	0.0005	0.2148	0.113	0.112	0.0029
animal	N	5	5	5	5	5
BNT162b1	%Diff	14.3	0.0	10.3	-14.9	-1.3
Group 7:	Mean	0.0126	1.0658	0.858	0.464	0.0118
100 µg/	SD	0.0015	0.3150	0.113	0.067	0.0008
animal	N	5	5	5	5	5
BNT162b2	%Diff	0.0	-17.7	4.9	-11.1	-22.4

[a] - Anova & Dunnett

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0440	0.0411	1.777	0.0438	0.0459	0.781
	SD	0.0048	0.0034	0.074	0.0116	0.0099	0.097
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.884	0.923	8.08	1.452	0.0142	0.0223
	SD	0.051	0.064	0.64	0.156	0.0054	0.0098
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0115	0.762	0.355	0.0093
	SD	0.0019	0.129	0.085	0.0018
	N	10	10	10	10
		-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a1]	Heart (g) [a1]
Group 1: Control	Mean	0.0453	0.0437	1.859	0.0539	0.0581	0.914
	SD	0.0090	0.0079	0.059	0.0156	0.0091	0.041
	N	10	10	10	10	10	10
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	0.0465	0.0463	1.839	0.0556	0.0538	0.863
	SD	0.0077	0.0045	0.091	0.0132	0.0189	0.059
	N	10	10	10	10	10	10
	%Diff	2.6	5.9	-1.1	3.2	-7.4	-5.6
Group 3: 10 µg/ animal BNT162a1	Mean	0.0454	0.0456	1.846	0.0578	0.0606	0.862
	SD	0.0083	0.0073	0.078	0.0108	0.0111	0.109
	N	10	10	10	10	10	10
	%Diff	0.2	4.3	-0.7	7.2	4.3	-5.7
Group 4: 30 µg/ animal BNT162b1	Mean	0.0455	0.0454	1.876	0.0559	0.0534	0.952
	SD	0.0050	0.0050	0.077	0.0067	0.0044	0.105
	N	10	10	10	10	10	10
	%Diff	0.4	3.9	0.9	3.7	-8.1	4.2

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a]	Heart (g) [a]
Group 5:	Mean	0.0516	0.0506	1.866	0.0545	0.0589	0.879
100 µg/	SD	0.0059	0.0074	0.087	0.0075	0.0116	0.073
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	13.9	15.8	0.4	1.1	1.4	-3.8
Group 7:	Mean	0.0494	0.0490	1.868	0.0492	0.0564	0.866
100 µg/	SD	0.0070	0.0066	0.072	0.0106	0.0114	0.065
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	9.1	12.1	0.5	-8.7	-2.9	-5.3

[a] - Anova & Dunnett

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a1]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a2]
Group 1: Control	Mean	0.938	0.989	8.35	1.333	0.0161	0.0339
	SD	0.077	0.076	0.61	0.096	0.0059	0.0175
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.991	1.019	9.12	1.489	0.0182	0.0280
	SD	0.046	0.038	0.34	0.174	0.0061	0.0128
	N	10	10	10	10	10	10
	%Diff	5.7	3.0	9.2	11.7	13.0	-17.4
Group 3: 10 µg/ animal BNT162a1	Mean	0.983	0.988	8.82	1.494	0.0190	0.0390
	SD	0.099	0.089	1.01	0.154	0.0050	0.0098
	N	10	10	10	10	10	10
	%Diff	4.8	-0.1	5.6	12.1	18.0	15.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.998	1.027	9.67**	1.565	0.0180	0.0325
	SD	0.077	0.078	1.25	0.168	0.0041	0.0223
	N	10	10	10	10	10	10
	%Diff	6.4	3.8	15.8	17.4	11.8	-4.1

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5:	Mean	1.044	1.079	10.07**	1.494	0.0173	0.0429
100 µg/	SD	0.101	0.095	1.25	0.207	0.0055	0.0165
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	11.3	9.1	20.6	12.1	7.5	26.5
Group 7:	Mean	1.009	1.057	9.95**	1.524	0.0167	0.0371
100 µg/	SD	0.075	0.088	0.69	0.170	0.0076	0.0244
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	7.6	6.9	19.2	14.3	3.7	9.4

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a1]
Group 1: Control	Mean	0.0150	0.595	0.456	0.0129
	SD	0.0022	0.135	0.089	0.0028
	N	10	10	10	10
		-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0129	0.941**	0.435	0.0121
	SD	0.0026	0.146	0.099	0.0039
	N	10	10	10	10
	%Diff	-14.0	58.2	-4.6	-6.2
Group 3: 10 µg/ animal BNT162a1	Mean	0.0149	0.734	0.487	0.0113
	SD	0.0021	0.051	0.105	0.0027
	N	10	10	10	10
	%Diff	-0.7	23.4	6.8	-12.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0140	0.777*	0.457	0.0094
	SD	0.0029	0.135	0.139	0.0013
	N	10	10	10	10
	%Diff	-6.7	30.6	0.2	-27.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log)

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5:	Mean	0.0143	0.921**	0.387	0.0094
100 µg/	SD	0.0022	0.151	0.081	0.0035
animal	N	10	9	10	10
BNT162b1	%Diff	-4.7	54.8	-15.1	-27.1
Group 7:	Mean	0.0143	0.957**	0.390	0.0109
100 µg/	SD	0.0023	0.130	0.108	0.0036
animal	N	10	10	10	10
BNT162b2	%Diff	-4.7	60.8	-14.5	-15.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0476	0.0462	1.850	0.0626	0.0636	0.902
	SD	0.0088	0.0058	0.090	0.0129	0.0166	0.091
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	1.002	1.026	8.52	1.344	0.0142	0.0404
	SD	0.141	0.115	0.81	0.166	0.0044	0.0105
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0152	0.564	0.428	0.0104
	SD	0.0028	0.084	0.060	0.0011
	N	5	5	5	5
		-	-	-	-

Three LNP-Formulated
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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a]	Heart (g) [a1]
Group 1: Control	Mean	0.0592	0.0586	1.924	0.0600	0.0696	0.998
	SD	0.0071	0.0063	0.097	0.0095	0.0160	0.041
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0478*	0.0448**	1.884	0.0570	0.0658	0.952
	SD	0.0047	0.0097	0.080	0.0130	0.0200	0.091
	N	5	5	5	5	5	5
	%Diff	-19.3	-23.5	-2.1	-5.0	-5.5	-4.6
Group 3: 10 µg/ animal BNT162a1	Mean	0.0438**	0.0428**	1.876	0.0588	0.0612	0.946
	SD	0.0063	0.0052	0.044	0.0192	0.0149	0.066
	N	5	5	5	5	5	5
	%Diff	-26.0	-27.0	-2.5	-2.0	-12.1	-5.2
Group 4: 30 µg/ animal BNT162b1	Mean	0.0476*	0.0436**	1.888	0.0632	0.0626	0.966
	SD	0.0051	0.0048	0.056	0.0197	0.0159	0.056
	N	5	5	5	5	5	5
	%Diff	-19.6	-25.6	-1.9	5.3	-10.1	-3.2

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a]	Heart (g) [a]
Group 5:	Mean	0.0508	0.0502	1.982	0.0666	0.0710	1.088
100 µg/	SD	0.0039	0.0033	0.057	0.0056	0.0100	0.195
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-14.2	-14.3	3.0	11.0	2.0	9.0
Group 7:	Mean	0.0494	0.0508	1.868	0.0512	0.0540	0.970
100 µg/	SD	0.0089	0.0070	0.033	0.0078	0.0095	0.078
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-16.6	-13.3	-2.9	-14.7	-22.4	-2.8

[a] - Anova & Dunnett

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RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a1]	Lymph node (mesent.) (g) [a]
Group 1: Control	Mean	1.066	1.128	10.04	1.576	0.0190	0.0344
	SD	0.097	0.132	0.64	0.143	0.0049	0.0152
	N	5	5	5	5	5	5
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	1.040	1.066	9.78	1.582	0.0180	0.0376
	SD	0.062	0.065	1.01	0.227	0.0065	0.0085
	N	5	5	5	5	5	5
	%Diff	-2.4	-5.5	-2.6	0.4	-5.3	9.3
Group 3: 10 µg/ animal BNT162a1	Mean	1.008	1.060	8.60	1.394	0.0172	0.0338
	SD	0.140	0.157	0.98	0.125	0.0053	0.0152
	N	5	5	5	5	5	5
	%Diff	-5.4	-6.0	-14.3	-11.5	-9.5	-1.7
Group 4: 30 µg/ animal BNT162b1	Mean	1.050	1.086	9.14	1.338	0.0186	0.0466
	SD	0.055	0.048	0.59	0.170	0.0061	0.0124
	N	5	5	5	5	5	5
	%Diff	-1.5	-3.7	-9.0	-15.1	-2.1	35.5

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Log)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5:	Mean	1.090	1.156	10.00	1.580	0.0264	0.0380
100 µg/	SD	0.156	0.162	1.07	0.191	0.0167	0.0099
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	2.3	2.5	-0.4	0.3	38.9	10.5
Group 7:	Mean	1.044	1.108	9.32	1.404	0.0150	0.0338
100 µg/	SD	0.143	0.094	0.88	0.083	0.0060	0.0169
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-2.1	-1.8	-7.2	-10.9	-21.1	-1.7

[a] - Anova & Dunnett

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 1: Control	Mean	0.0174	0.712	0.510	0.0156
	SD	0.0021	0.103	0.099	0.0023
	N	5	5	5	5
		-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0168	0.644	0.422	0.0148
	SD	0.0013	0.094	0.076	0.0041
	N	5	5	5	5
	%Diff	-3.4	-9.6	-17.3	-5.1
Group 3: 10 µg/ animal BNT162a1	Mean	0.0142	0.604	0.450	0.0118
	SD	0.0028	0.024	0.124	0.0032
	N	5	5	5	5
	%Diff	-18.4	-15.2	-11.8	-24.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0148	0.590	0.402	0.0128
	SD	0.0029	0.063	0.074	0.0024
	N	5	5	5	5
	%Diff	-14.9	-17.1	-21.2	-17.9

[a] - Anova & Dunnett

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5:	Mean	0.0156	0.734	0.486	0.0112
100 µg/	SD	0.0026	0.093	0.093	0.0018
animal	N	5	5	5	5
BNT162b1	%Diff	-10.3	3.1	-4.7	-28.2
Group 7:	Mean	0.0162	0.674	0.402	0.0106
100 µg/	SD	0.0026	0.072	0.085	0.0030
animal	N	5	5	5	5
BNT162b2	%Diff	-6.9	-5.3	-21.2	-32.1

[a] - Anova & Dunnett

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	3	Male	Epididymis - Left	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Epididymis - Right	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	5	Male	Epididymis - Right	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Epididymis - Left	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Epididymis - Right	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Liver	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Liver	**	Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	3	Male	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Thymus Weight	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Male	Adrenal Wt left	*	Anova & Dunnett: * = p ≤ 0.05
	38	3	Male	Epididymis - Right	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	38	5	Male	Epididymis - Right	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	3	Male	Lymph node (mesent.)	*	Anova & Dunnett: * = p ≤ 0.05
	38	5	Male	Lymph node (mesent.)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Female	Liver	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Spleen Weight	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Female	Adrenal Wt left	*	Anova & Dunnett: * = p ≤ 0.05
	38	2	Female	Adrenal Wt right	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	Adrenal Wt left	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	Adrenal Wt right	**	Anova & Dunnett: ** = p ≤ 0.01
	38	4	Female	Adrenal Wt left	*	Anova & Dunnett: * = p ≤ 0.05
	38	4	Female	Adrenal Wt right	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
151	0.042	0.038	1.91	0.51	0.54	1.84	2.13
152	0.040	0.043	1.94	0.56	0.51	1.85	1.79
153	0.040	0.042	1.88	0.49	0.57	1.73	1.76
154	0.040	0.038	2.06	0.47	0.45	1.96	1.97
155	0.039	0.044	2.05	0.42	0.40	1.75	1.74
156	0.044	0.041	2.00	0.53	0.52	1.72	1.61
157	0.045	0.044	2.04	0.43	0.48	1.76	1.82
158	0.042	0.036	1.89	0.34	0.35	1.53	1.61
159	0.038	0.032	2.02	0.48	0.44	1.71	1.70
160	0.029	0.031	1.83	0.36	0.42	1.65	1.64
Mean	0.0399	0.0389	1.962	0.459	0.468	1.750	1.777
SD	0.0044	0.0047	0.082	0.071	0.068	0.117	0.165
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
151	1.09	1.25	1.22	11.0	1.66	0.012	0.036
152	1.15	1.58	1.56	11.5	1.86	0.016	0.026
153	0.96	1.38	1.40	9.9	1.62	0.020	0.043
154	1.09	1.42	1.35	11.2	1.90	0.020	0.031
155	1.05	1.36	1.42	11.7	1.97	0.021	0.026
156	1.11	1.35	1.26	11.1	1.60	0.013	0.027
157	1.07	1.37	1.43	12.3	1.57	0.016	0.030
158	1.38	1.33	1.28	10.5	1.71	0.018	0.012
159	1.01	1.26	1.34	11.3	1.52	0.019	0.051
160	0.99	1.21	1.17	9.8	1.61	0.018	0.047
Mean	1.090	1.351	1.343	11.03	1.702	0.0173	0.0329
SD	0.117	0.104	0.115	0.78	0.154	0.0030	0.0116
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
151	0.011	0.742	0.92	0.64	0.016
152	0.012	1.088	1.09	0.54	0.015
153	0.009	0.791	0.89	0.41	0.006
154	0.011	1.072	1.30	0.44	0.009
155	0.011	0.835	1.24	0.66	0.013
156	0.009	0.703	0.88	0.42	0.012
157	0.010	0.656	0.94	0.37	0.008
158	0.008	0.679	0.92	0.40	0.011
159	0.011	0.653	0.97	0.42	0.012
160	0.009	0.567	1.09	0.35	0.008
Mean	0.0101	0.7786	1.024	0.465	0.0110
SD	0.0013	0.1757	0.150	0.110	0.0032
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
166	0.043	0.045	1.74	0.039	0.042	0.88
167	0.041	0.040	1.87	0.040	0.043	0.80
168	0.042	0.039	1.77	0.049	0.062	0.69
169	0.048	0.045	1.83	0.065	0.061	0.75
170	0.035	0.035	1.83	0.044	0.043	1.00
171	0.045	0.039	1.83	0.020	0.028	0.72
172	0.040	0.041	1.68	0.046	0.046	0.78
173	0.049	0.046	1.64	0.054	0.046	0.73
174	0.046	0.040	1.82	0.039	0.040	0.68
175	0.051	0.041	1.76	0.042	0.048	0.78
Mean	0.0440	0.0411	1.777	0.0438	0.0459	0.781
SD	0.0048	0.0034	0.074	0.0116	0.0099	0.097
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
166	0.85	0.96	8.8	1.47	0.005	0.015
167	0.93	0.99	8.2	1.55	0.012	0.020
168	0.88	0.94	7.2	1.10	0.012	0.024
169	0.97	1.00	8.5	1.46	0.024	0.036
170	0.92	0.90	8.3	1.53	0.020	0.039
171	0.82	0.90	7.2	1.48	0.018	0.017
172	0.84	0.80	8.3	1.55	0.011	0.014
173	0.92	0.96	8.9	1.39	0.014	0.015
174	0.82	0.84	7.3	1.32	0.011	0.031
175	0.89	0.94	8.1	1.67	0.015	0.012
Mean	0.884	0.923	8.08	1.452	0.0142	0.0223
SD	0.051	0.064	0.64	0.156	0.0054	0.0098
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
166	0.012	0.78	0.47	0.006
167	0.011	0.66	0.35	0.008
168	0.009	0.61	0.32	0.009
169	0.015	0.66	0.39	0.012
170	0.013	0.89	0.43	0.009
171	0.012	0.77	0.18	0.011
172	0.009	0.83	0.26	0.010
173	0.010	0.94	0.39	0.011
174	0.013	0.58	0.35	0.009
175	0.011	0.90	0.41	0.008
Mean	0.0115	0.762	0.355	0.0093
SD	0.0019	0.129	0.085	0.0018
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
1	0.034	0.030	1.97	0.58	0.42	1.84	1.85
2	0.040	0.035	1.95	0.45	0.39	2.01	1.92
3	0.044	0.039	2.12	0.55	0.45	1.75	1.73
4	0.035	0.036	1.95	0.40	0.41	1.73	1.60
5	0.034	0.038	1.91	0.36	0.39	1.66	1.68
6	0.037	0.029	2.03	0.39	0.41	1.77	1.81
7	0.035	0.030	2.05	0.45	0.47	1.63	1.65
8	0.049	0.046	2.00	0.53	0.48	1.97	1.93
9	0.039	0.035	2.08	0.41	0.38	1.81	1.84
10	0.034	0.035	1.98	0.45	0.39	1.80	1.75
Mean	0.0381	0.0353	2.004	0.457	0.419	1.797	1.776
SD	0.0050	0.0051	0.065	0.073	0.036	0.121	0.113
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
31	0.040	0.037	1.94	0.44	0.40	1.83	1.77
32	0.046	0.040	1.91	0.46	0.49	1.74	1.73
33	0.055	0.060	2.05	0.49	0.43	1.83	1.87
34	0.045	0.043	1.83	0.48	0.44	1.77	1.80
35	0.036	0.040	1.92	0.49	0.44	1.73	1.72
36	0.039	0.031	2.01	0.44	0.38	1.61	1.57
37	0.039	0.035	1.98	0.37	0.41	1.74	1.82
38	0.035	0.042	2.00	0.48	0.49	1.80	1.87
39	0.041	0.041	1.95	0.39	0.44	1.73	1.72
40	0.039	0.039	1.91	0.45	0.47	1.63	1.69
Mean	0.0415	0.0408	1.950	0.449	0.439	1.741	1.756
SD	0.0059	0.0076	0.063	0.041	0.037	0.074	0.091
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
61	0.038	0.042	1.98	0.64	0.60	2.09	2.13
62	0.038	0.042	1.89	0.43	0.42	1.77	1.77
63	0.038	0.039	1.92	0.77	0.68	2.14	2.07
64	0.035	0.039	1.97	0.58	0.59	1.82	1.84
65	0.040	0.036	1.95	0.52	0.47	1.97	1.96
66	0.037	0.032	2.17	0.60	0.56	1.84	1.76
67	0.046	0.045	2.03	0.68	0.63	1.89	2.00
68	0.033	0.037	1.89	0.54	0.42	1.78	1.68
69	0.044	0.046	1.94	0.49	0.44	1.58	1.60
70	0.057	0.055	2.04	0.52	0.43	1.82	1.83
Mean	0.0406	0.0413	1.978	0.577	0.524	1.870	1.864
SD	0.0069	0.0064	0.085	0.100	0.099	0.163	0.172
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
91	0.034	0.028	1.92	0.47	0.41	1.84	1.79
92	0.039	0.035	2.03	0.47	0.45	1.61	1.63
93	0.038	0.033	1.88	0.50	0.46	1.80	1.72
94	0.041	0.043	1.88	0.38	0.41	1.65	1.63
95	0.048	0.048	1.90	0.51	0.41	1.82	1.81
96	0.047	0.041	2.01	0.54	0.54	1.83	1.80
97	0.042	0.033	2.02	0.49	0.49	1.72	1.66
98	0.048	0.051	1.98	0.53	0.50	1.96	2.00
99	0.039	0.039	2.02	0.57	0.54	1.91	1.89
100	0.042	0.041	1.97	0.44	0.41	1.71	1.73
Mean	0.0418	0.0392	1.961	0.490	0.462	1.785	1.766
SD	0.0047	0.0071	0.061	0.054	0.053	0.111	0.118
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
121	0.030	0.037	2.11	0.71	0.61	2.14	2.09
122	0.033	0.034	1.90	0.48	0.46	1.64	1.71
123	0.051	0.057	1.98	0.48	0.52	2.12	1.86
124	0.033	0.040	2.18	0.51	0.55	1.82	1.84
125	0.053	0.043	2.03	0.52	0.71	1.69	1.73
126	0.046	0.042	1.92	0.54	0.51	1.75	1.69
127	0.052	0.055	1.88	0.54	0.47	1.71	1.72
128	0.042	0.035	1.92	0.49	0.45	2.02	1.91
129	0.041	0.039	1.94	0.52	0.52	1.81	1.80
130	0.046	0.043	1.91	0.54	0.59	1.70	1.66
Mean	0.0427	0.0425	1.977	0.533	0.539	1.840	1.801
SD	0.0084	0.0078	0.100	0.067	0.080	0.185	0.130
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
181	0.039	0.037	1.95	0.53	0.56	1.97	2.00
182	0.032	0.031	1.91	0.44	0.44	1.59	1.64
183	0.040	0.034	1.95	0.53	0.44	1.75	1.75
184	0.050	0.051	1.95	0.44	0.40	1.72	1.68
185	0.049	0.045	1.91	0.53	0.56	1.99	2.00
186	0.040	0.034	1.95	0.51	0.50	1.91	1.77
187	0.045	0.014	1.97	0.51	0.45	1.78	1.72
188	0.043	0.037	1.89	0.61	0.53	1.96	2.01
189	0.036	0.035	2.01	0.63	0.52	1.97	1.89
190	0.056	0.055	1.95	0.81	0.74	1.79	1.72
Mean	0.0430	0.0373	1.944	0.554	0.514	1.843	1.818
SD	0.0072	0.0114	0.034	0.109	0.097	0.136	0.143
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
1	1.15	1.49	1.56	12.5	1.65	0.020	0.033
2	1.07	1.41	1.50	12.8	1.97	0.018	0.042
3	1.20	1.44	1.46	14.2	1.86	0.023	0.064
4	1.09	1.51	1.63	12.5	1.66	0.013	0.021
5	1.08	1.32	1.36	12.5	1.61	0.045	0.020
6	1.18	1.38	1.41	13.5	1.68	0.009	0.011
7	1.15	1.35	1.31	13.1	3.31	0.014	0.031
8	1.21	1.35	1.39	12.8	1.87	0.028	0.034
9	1.11	1.60	1.61	13.3	2.03	0.017	0.021
10	1.16	1.41	1.56	13.0	1.72	0.022	0.053
Mean	1.140	1.426	1.479	13.02	1.936	0.0209	0.0330
SD	0.050	0.086	0.110	0.54	0.504	0.0101	0.0163
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
31	1.07	1.33	1.32	10.3	1.83	0.023	0.067
32	0.94	1.50	1.52	10.9	1.92	0.019	0.058
33	1.21	1.51	1.56	12.5	2.10	0.022	0.036
34	0.98	1.32	1.31	11.2	1.85	0.017	0.022
35	1.27	1.34	1.27	11.6	1.68	0.017	0.046
36	1.02	1.20	1.23	11.1	1.68	0.017	0.030
37	1.00	1.21	1.25	10.1	1.91	0.018	0.017
38	1.51	1.41	1.44	8.9	2.44	0.021	0.053
39	0.95	1.19	1.34	9.4	1.49	0.019	0.031
40	1.01	1.08	1.10	9.8	1.63	0.025	0.027
Mean	1.096	1.309	1.334	10.58	1.853	0.0198	0.0387
SD	0.182	0.140	0.139	1.09	0.270	0.0028	0.0165
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
61	1.16	1.41	1.49	13.1	1.93	0.019	0.035
62	0.96	1.38	1.42	12.6	1.86	0.016	0.053
63	1.16	1.42	1.53	12.3	2.04	0.013	0.025
64	1.13	1.47	1.51	11.5	1.78	0.020	0.045
65	1.19	1.59	1.50	14.6	1.85	0.020	0.053
66	1.29	1.50	1.47	13.1	2.03	0.025	0.029
67	1.16	1.51	1.65	13.1	2.32	0.021	0.038
68	1.04	1.28	1.18	11.0	1.76	0.021	0.017
69	1.32	1.40	1.41	12.6	2.17	0.019	0.020
70	1.23	1.34	1.45	13.9	2.45	0.014	0.084
Mean	1.164	1.430	1.461	12.78	2.019	0.0188	0.0399
SD	0.107	0.090	0.120	1.05	0.232	0.0036	0.0200
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
91	1.25	1.38	1.40	11.6	2.04	0.023	0.049
92	0.99	1.36	1.41	10.0	1.49	0.013	0.067
93	1.09	1.42	1.27	11.6	1.85	0.016	0.036
94	1.19	1.42	1.51	12.7	1.94	0.009	0.011
95	1.17	1.47	1.45	12.0	1.74	0.012	0.020
96	1.10	1.46	1.49	12.9	1.96	0.082	0.050
97	1.00	1.25	1.45	11.2	1.62	0.018	0.022
98	1.05	1.49	1.39	11.8	1.65	0.017	0.027
99	1.00	1.47	1.42	12.2	1.77	0.019	0.043
100	1.11	1.32	1.39	11.2	1.81	0.021	0.009
Mean	1.095	1.404	1.418	11.72	1.787	0.0230	0.0334
SD	0.088	0.077	0.066	0.83	0.170	0.0212	0.0188
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
121	1.54	1.46	1.48	13.2	1.95	0.019	0.021
122	1.01	1.41	1.31	11.2	2.06	0.008	0.082
123	1.14	1.46	1.44	12.9	1.90	0.010	0.027
124	1.33	1.67	1.75	15.2	2.37	0.019	0.027
125	1.04	1.37	1.35	12.0	1.68	0.022	0.050
126	1.27	1.63	1.63	16.2	2.16	0.034	0.070
127	1.10	1.57	1.41	12.0	1.76	0.026	0.039
128	1.01	1.16	1.19	12.1	1.77	0.020	0.064
129	1.14	1.49	1.47	11.3	1.63	0.015	0.034
130	1.09	1.61	1.63	15.7	1.84	0.014	0.026
Mean	1.167	1.483	1.466	13.18	1.912	0.0187	0.0440
SD	0.168	0.150	0.167	1.86	0.230	0.0076	0.0214
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
181	1.29	1.41	1.47	12.9	1.85	0.014	0.017
182	0.97	1.31	1.39	10.4	1.73	0.017	0.046
183	1.00	1.34	1.42	12.4	1.84	0.012	0.094
184	1.34	1.35	1.37	11.8	1.64	0.018	0.025
185	1.17	1.47	1.42	14.4	2.13	0.023	0.053
186	1.02	1.39	1.43	11.5	1.71	0.022	0.086
187	1.10	1.22	1.27	11.6	2.14	0.015	0.064
188	1.21	1.38	1.44	12.4	1.74	0.009	0.024
189	1.14	1.53	1.59	11.4	1.68	0.015	0.049
190	1.11	1.50	1.51	12.8	2.31	0.012	0.036
Mean	1.135	1.390	1.431	12.16	1.877	0.0157	0.0494
SD	0.122	0.093	0.085	1.09	0.232	0.0044	0.0259
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
1	0.014	0.628	0.69	0.45	0.013
2	0.012	1.032	0.88	0.58	0.018
3	0.015	0.928	0.82	0.65	0.012
4	0.013	1.120	0.63	0.41	0.013
5	0.010	0.952	0.77	0.48	0.015
6	0.012	0.728	0.96	0.57	0.011
7	0.011	0.907	0.94	0.55	0.008
8	0.013	1.208	1.04	0.53	0.011
9	0.013	0.900	0.84	0.73	0.016
10	0.015	0.871	0.81	0.43	0.014
Mean	0.0128	0.9274	0.838	0.538	0.0131
SD	0.0016	0.1703	0.124	0.101	0.0028
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
31	0.011	0.852	1.13	0.43	0.015
32	0.012	0.641	0.74	0.48	0.014
33	0.012	0.734	1.14	0.64	0.014
34	0.012	0.813	1.09	0.44	0.014
35	0.013	1.341	1.05	0.58	0.011
36	0.017	0.701	0.99	0.48	0.012
37	0.015	0.623	0.91	0.32	0.018
38	0.009	0.607	0.89	0.47	0.014
39	0.011	0.690	0.84	0.32	0.013
40	0.011	0.884	0.98	0.47	0.013
Mean	0.0123	0.7886	0.976	0.463	0.0138
SD	0.0023	0.2164	0.131	0.099	0.0019
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
61	0.014	0.761	1.07	0.41	0.011
62	0.009	0.668	0.90	0.56	0.013
63	0.014	1.085	1.18	0.41	0.013
64	0.012	0.797	1.03	0.43	0.012
65	0.011	0.718	1.00	0.63	0.008
66	0.014	1.081	1.07	0.42	0.011
67	0.016	1.104	1.27	0.58	0.021
68	0.014	0.993	0.83	0.50	0.011
69	0.014	0.952	1.15	0.73	0.013
70	0.012	0.617	1.29	0.60	0.011
Mean	0.0130	0.8776	1.079	0.527	0.0124
SD	0.0020	0.1862	0.149	0.111	0.0034
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
91	0.012	0.782	1.01	0.47	0.015
92	0.014	0.684	0.73	0.40	0.014
93	0.010	1.001	0.93	0.53	0.016
94	0.010	0.831	0.97	0.51	0.011
95	0.016	0.919	0.89	0.62	0.010
96	0.016	0.854	1.12	0.55	0.014
97	0.011	0.825	0.95	0.37	0.011
98	0.012	0.748	1.08	0.55	0.012
99	0.014	1.213	0.95	0.40	0.015
100	0.011	0.608	0.88	0.28	0.016
Mean	0.0126	0.8465	0.951	0.468	0.0134
SD	0.0023	0.1704	0.109	0.103	0.0022
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
121	0.016	0.703	1.22	0.51	0.014
122	0.007	0.541	0.91	0.39	0.009
123	0.011	0.914	1.15	0.48	0.010
124	0.012	1.013	1.02	0.56	0.013
125	0.014	0.708	0.97	0.36	0.012
126	0.014	0.843	1.28	0.40	0.013
127	0.014	1.000	0.83	0.37	0.010
128	0.009	0.358	1.01	0.32	0.007
129	0.011	NT !	0.90	0.36	0.010
130	0.011	1.027	1.01	0.60	0.007
Mean	0.0119	0.7897	1.030	0.435	0.0105
SD	0.0027	0.2321	0.145	0.096	0.0025
N	10	9	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
181	0.013	0.958	1.15	0.27	0.007
182	0.011	0.664	0.86	0.34	0.013
183	0.013	0.976	0.99	0.30	0.007
184	0.012	0.597	1.05	0.39	0.014
185	0.011	1.190	1.22	0.34	0.010
186	0.010	0.781	0.96	0.23	0.013
187	0.011	0.682	0.96	0.26	0.010
188	0.009	0.755	0.99	0.93	0.008
189	0.012	0.978	1.16	0.39	0.014
190	0.011	0.549	1.15	0.43	0.013
Mean	0.0113	0.8130	1.049	0.388	0.0109
SD	0.0013	0.2047	0.116	0.201	0.0028
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
16	0.059	0.056	1.95	0.054	0.060	0.91
17	0.047	0.048	1.82	0.086	0.072	0.91
18	0.028	0.031	1.74	0.066	0.068	0.90
19	0.036	0.034	1.88	0.027	0.060	1.00
20	0.042	0.049	1.90	0.052	0.059	0.86
21	0.041	0.037	1.86	0.057	0.044	0.92
22	0.053	0.050	1.83	0.041	0.060	0.95
23	0.049	0.041	1.83	0.051	0.062	0.90
24	0.046	0.044	1.92	0.059	0.044	0.93
25	0.052	0.047	1.86	0.046	0.052	0.86
Mean	0.0453	0.0437	1.859	0.0539	0.0581	0.914
SD	0.0090	0.0079	0.059	0.0156	0.0091	0.041
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
46	0.054	0.051	1.77	0.064	0.090	0.86
47	0.038	0.040	1.87	0.046	0.034	0.90
48	0.051	0.045	1.77	0.062	0.029	0.95
49	0.033	0.050	1.98	0.037	0.040	0.78
50	0.057	0.050	1.83	0.051	0.047	0.82
51	0.050	0.047	1.87	0.040	0.044	0.85
52	0.043	0.037	1.89	0.048	0.053	0.94
53	0.040	0.047	1.85	0.064	0.064	0.89
54	0.048	0.049	1.91	0.079	0.066	0.86
55	0.051	0.047	1.65	0.065	0.071	0.78
Mean	0.0465	0.0463	1.839	0.0556	0.0538	0.863
SD	0.0077	0.0045	0.091	0.0132	0.0189	0.059
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
76	0.039	0.039	1.73	0.070	0.058	0.91
77	0.047	0.047	1.94	0.044	0.046	0.80
78	0.039	0.041	1.73	0.048	0.059	0.77
79	0.064	0.062	1.88	0.055	0.052	0.99
80	0.049	0.039	1.81	0.075	0.058	0.74
81	0.052	0.046	1.90	0.063	0.071	0.87
82	0.047	0.043	1.91	0.068	0.086	1.08
83	0.040	0.041	1.86	0.055	0.060	0.76
84	0.040	0.044	1.78	0.045	0.054	0.88
85	0.037	0.054	1.92	0.055	0.062	0.82
Mean	0.0454	0.0456	1.846	0.0578	0.0606	0.862
SD	0.0083	0.0073	0.078	0.0108	0.0111	0.109
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
106	0.042	0.044	1.81	0.049	0.048	0.94
107	0.050	0.050	1.96	0.061	0.048	0.91
108	0.042	0.040	1.81	0.051	0.056	0.82
109	0.044	0.041	1.99	0.047	0.053	1.19
110	0.049	0.056	1.79	0.051	0.051	0.92
111	0.042	0.043	1.83	0.064	0.059	1.03
112	0.057	0.050	1.84	0.059	0.048	0.96
113	0.045	0.044	1.94	0.067	0.056	0.98
114	0.042	0.044	1.83	0.053	0.059	0.94
115	0.042	0.042	1.96	0.057	0.056	0.83
Mean	0.0455	0.0454	1.876	0.0559	0.0534	0.952
SD	0.0050	0.0050	0.077	0.0067	0.0044	0.105
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
136	0.059	0.054	2.04	0.045	0.045	1.04
137	0.053	0.048	1.82	0.064	0.073	0.77
138	0.050	0.054	1.74	0.056	0.051	0.81
139	0.045	0.041	1.86	0.056	0.055	0.86
140	0.048	0.047	1.84	0.050	0.062	0.91
141	0.050	0.054	1.88	0.053	0.049	0.92
142	0.051	0.045	1.98	0.054	0.069	0.90
143	0.045	0.042	1.82	0.042	0.046	0.86
144	0.051	0.056	1.81	0.065	0.078	0.84
145	0.064	0.065	1.87	0.060	0.061	0.88
Mean	0.0516	0.0506	1.866	0.0545	0.0589	0.879
SD	0.0059	0.0074	0.087	0.0075	0.0116	0.073
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
196	0.040	0.050	1.91	0.044	0.058	0.96
197	0.050	0.047	1.84	0.051	0.044	0.88
198	0.040	0.036	1.75	0.063	0.067	0.84
199	0.060	0.055	1.80	0.048	0.077	0.77
200	0.060	0.059	1.89	0.030	0.050	0.84
201	0.050	0.048	1.96	0.046	0.047	0.87
202	0.053	0.054	1.89	0.057	0.056	0.79
203	0.048	0.052	1.91	0.066	0.060	0.86
204	0.044	0.043	1.78	0.045	0.065	0.98
205	0.049	0.046	1.95	0.042	0.040	0.87
Mean	0.0494	0.0490	1.868	0.0492	0.0564	0.866
SD	0.0070	0.0066	0.072	0.0106	0.0114	0.065
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
16	1.12	1.07	9.6	1.38	0.012	0.021
17	0.90	1.03	8.0	1.25	0.031	0.036
18	0.89	0.93	7.4	1.33	0.014	0.049
19	0.88	0.86	8.9	1.54	0.017	0.018
20	0.86	0.91	7.9	1.38	0.010	0.015
21	0.90	0.99	8.0	1.18	0.015	0.029
22	0.97	0.94	8.3	1.30	0.018	0.044
23	0.91	1.03	8.2	1.28	0.014	0.042
24	0.99	1.09	8.5	1.32	0.018	0.069
25	0.96	1.04	8.7	1.37	0.012	0.016
Mean	0.938	0.989	8.35	1.333	0.0161	0.0339
SD	0.077	0.076	0.61	0.096	0.0059	0.0175
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
46	1.07	1.10	9.5	1.47	0.024	0.039
47	1.00	1.04	9.2	1.63	0.021	0.018
48	0.95	1.01	9.6	1.35	0.008	0.054
49	1.06	1.04	8.5	1.46	0.016	0.017
50	0.99	1.01	8.8	1.64	0.014	0.024
51	0.98	0.97	9.4	1.39	0.011	0.017
52	1.01	1.00	9.0	1.78	0.017	0.018
53	0.97	1.03	9.2	1.15	0.021	0.020
54	0.94	0.97	9.1	1.51	0.028	0.038
55	0.94	1.02	8.9	1.51	0.022	0.035
Mean	0.991	1.019	9.12	1.489	0.0182	0.0280
SD	0.046	0.038	0.34	0.174	0.0061	0.0128
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
76	0.94	0.99	9.3	1.62	0.023	0.041
77	1.06	1.00	9.0	1.64	0.029	0.055
78	0.92	0.93	8.1	1.27	0.020	0.045
79	1.15	1.14	10.1	1.55	0.021	0.027
80	0.92	0.91	7.5	1.28	0.018	0.030
81	1.02	0.96	9.2	1.49	0.011	0.030
82	1.12	1.12	10.3	1.74	0.015	0.054
83	0.95	0.86	7.7	1.45	0.016	0.036
84	0.89	0.94	9.3	1.52	0.021	0.034
85	0.86	1.03	7.7	1.38	0.016	0.038
Mean	0.983	0.988	8.82	1.494	0.0190	0.0390
SD	0.099	0.089	1.01	0.154	0.0050	0.0098
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
106	1.06	1.10	9.7	1.44	0.021	0.054
107	1.01	1.02	8.5	1.53	0.017	0.013
108	0.98	1.00	9.0	1.43	0.011	0.030
109	1.10	1.14	12.0	1.86	0.023	0.024
110	0.91	0.94	9.6	1.32	0.023	0.019
111	1.10	1.14	9.7	1.72	0.014	0.012
112	0.94	0.99	9.4	1.59	0.017	0.021
113	1.05	1.05	11.6	1.72	0.021	0.019
114	0.94	0.96	9.2	1.62	0.019	0.079
115	0.89	0.93	8.0	1.42	0.014	0.054
Mean	0.998	1.027	9.67	1.565	0.0180	0.0325
SD	0.077	0.078	1.25	0.168	0.0041	0.0223
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
136	1.23	1.13	11.7	1.71	0.026	0.038
137	0.93	0.98	8.9	1.47	0.015	0.032
138	0.93	1.00	8.9	1.41	0.011	0.034
139	0.98	1.02	8.7	1.58	0.014	0.051
140	1.00	1.00	9.4	1.39	0.018	0.015
141	1.14	1.22	10.6	1.66	0.010	0.045
142	0.95	0.98	9.1	1.47	0.023	0.028
143	1.08	1.09	10.8	1.32	0.020	0.055
144	1.11	1.16	12.2	1.11	0.013	0.065
145	1.09	1.21	10.4	1.82	0.023	0.066
Mean	1.044	1.079	10.07	1.494	0.0173	0.0429
SD	0.101	0.095	1.25	0.207	0.0055	0.0165
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
196	1.07	1.09	11.1	1.80	0.005	0.023
197	0.96	1.00	9.6	1.52	0.007	0.012
198	0.88	0.94	9.9	1.27	0.022	0.034
199	0.91	0.97	8.7	1.32	0.023	0.043
200	1.00	1.17	10.2	1.70	0.011	0.056
201	1.12	0.98	10.5	1.51	0.015	0.021
202	1.05	1.00	9.1	1.42	0.022	0.025
203	1.00	1.17	10.2	1.66	0.026	0.095
204	1.07	1.14	9.9	1.43	0.012	0.043
205	1.03	1.11	10.3	1.61	0.024	0.019
Mean	1.009	1.057	9.95	1.524	0.0167	0.0371
SD	0.075	0.088	0.69	0.170	0.0076	0.0244
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
16	0.015	0.49	0.46	0.011
17	0.015	0.58	0.52	0.013
18	0.012	0.46	0.65	0.009
19	0.014	0.95	0.32	0.015
20	0.018	0.58	0.43	0.011
21	0.013	0.53	0.50	0.011
22	0.016	0.53	0.43	0.019
23	0.015	0.62	0.37	0.014
24	0.019	0.61	0.45	0.014
25	0.013	0.60	0.43	0.012
Mean	0.0150	0.595	0.456	0.0129
SD	0.0022	0.135	0.089	0.0028
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
46	0.015	0.92	0.54	0.012
47	0.009	0.76	0.53	0.007
48	0.014	0.91	0.42	0.012
49	0.011	1.00	0.53	0.012
50	0.014	1.03	0.28	0.017
51	0.013	0.83	0.50	0.007
52	0.011	1.23	0.47	0.016
53	0.013	1.00	0.32	0.010
54	0.018	1.00	0.31	0.018
55	0.011	0.73	0.45	0.010
Mean	0.0129	0.941	0.435	0.0121
SD	0.0026	0.146	0.099	0.0039
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
76	0.015	0.75	0.50	0.011
77	0.015	0.69	0.53	0.008
78	0.014	0.69	0.50	0.013
79	0.015	0.71	0.48	0.013
80	0.014	0.68	0.40	0.014
81	0.012	0.70	0.45	0.009
82	0.019	0.84	0.60	0.010
83	0.012	0.79	0.33	0.011
84	0.017	0.76	0.69	0.008
85	0.016	0.73	0.39	0.016
Mean	0.0149	0.734	0.487	0.0113
SD	0.0021	0.051	0.105	0.0027
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
106	0.016	0.77	0.49	0.010
107	0.015	0.67	0.51	0.009
108	0.010	0.75	0.43	0.010
109	0.014	0.97	0.75	0.012
110	0.020	0.77	0.31	0.009
111	0.014	1.00	0.55	0.009
112	0.015	0.59	0.32	0.009
113	0.014	0.88	0.52	0.007
114	0.010	0.72	0.40	0.009
115	0.012	0.65	0.29	0.010
Mean	0.0140	0.777	0.457	0.0094
SD	0.0029	0.135	0.139	0.0013
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
136	0.017	1.17	0.55	0.007
137	0.017	0.83	0.31	0.017
138	0.012	0.62	0.30	0.008
139	0.015	0.89	0.38	0.012
140	0.013	0.99	0.35	0.005
141	0.014	1.01	0.32	0.007
142	0.015	0.86	0.35	0.010
143	0.014	0.95	0.49	0.007
144	0.010	NT !	0.42	0.009
145	0.016	0.97	0.40	0.012
Mean	0.0143	0.921	0.387	0.0094
SD	0.0022	0.151	0.081	0.0035
N	10	9	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
196	0.014	1.19	0.38	0.011
197	0.014	0.93	0.33	0.008
198	0.012	0.93	0.36	0.009
199	0.017	0.73	0.32	0.016
200	0.014	0.88	0.35	0.008
201	0.011	0.93	0.64	0.018
202	0.019	0.92	0.44	0.012
203	0.015	0.89	0.44	0.007
204	0.013	1.07	0.41	0.010
205	0.014	1.10	0.23	0.010
Mean	0.0143	0.957	0.390	0.0109
SD	0.0023	0.130	0.108	0.0036
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
161	0.045	0.043	1.87	0.64	0.68	1.76	1.78
162	0.033	0.030	2.11	0.61	0.65	1.86	1.85
163	0.032	0.035	2.07	0.63	0.67	1.94	1.98
164	0.032	0.040	1.96	0.72	0.73	1.89	2.57
165	0.043	0.034	2.10	0.64	0.69	1.99	1.99
Mean	0.0370	0.0364	2.022	0.648	0.684	1.888	2.034
SD	0.0064	0.0051	0.104	0.042	0.030	0.087	0.312
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
161	1.48	1.64	1.79	14.8	2.33	0.016	0.035
162	1.12	1.50	1.50	11.4	1.63	0.012	0.023
163	1.36	1.48	1.39	13.6	2.50	0.026	0.065
164	1.03	1.42	1.50	12.5	1.83	0.013	0.035
165	1.41	1.68	1.80	13.3	2.93	0.024	0.049
Mean	1.280	1.544	1.596	13.12	2.244	0.0182	0.0414
SD	0.195	0.111	0.187	1.27	0.522	0.0064	0.0161
N	5	5	5	5	5	5	5

TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
161	0.014	1.162	0.85	0.36	0.018
162	0.012	1.083	0.64	0.31	0.011
163	0.016	0.956	1.04	0.47	0.019
164	0.010	0.958	0.75	0.43	0.008
165	0.012	0.905	0.85	0.47	0.018
Mean	0.0128	1.0128	0.826	0.408	0.0148
SD	0.0023	0.1061	0.148	0.071	0.0050
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
176	0.048	0.048	1.71	0.066	0.058	0.81
177	0.055	0.047	1.92	0.057	0.072	0.87
178	0.042	0.038	1.81	0.043	0.043	0.92
179	0.036	0.044	1.92	0.075	0.058	0.86
180	0.057	0.054	1.89	0.072	0.087	1.05
Mean	0.0476	0.0462	1.850	0.0626	0.0636	0.902
SD	0.0088	0.0058	0.090	0.0129	0.0166	0.091
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
176	0.91	0.95	7.8	1.31	0.011	0.034
177	0.92	0.94	8.1	1.19	0.013	0.055
178	0.96	0.98	8.5	1.25	0.022	0.046
179	0.97	1.04	8.3	1.35	0.013	0.028
180	1.25	1.22	9.9	1.62	0.012	0.039
Mean	1.002	1.026	8.52	1.344	0.0142	0.0404
SD	0.141	0.115	0.81	0.166	0.0044	0.0105
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
176	0.018	0.61	0.50	0.009
177	0.015	0.49	0.36	0.010
178	0.018	0.51	0.41	0.012
179	0.012	0.52	0.39	0.011
180	0.013	0.69	0.48	0.010
Mean	0.0152	0.564	0.428	0.0104
SD	0.0028	0.084	0.060	0.0011
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
11	0.035	0.040	2.16	0.65	0.62	2.16	2.18
12	0.043	0.045	2.09	0.72	0.68	1.94	1.88
13	0.044	0.043	2.02	0.84	0.74	1.96	1.97
14	0.028	0.030	1.99	0.73	0.67	1.90	1.96
15	0.041	0.034	2.12	0.64	0.60	2.58	3.67 >
Mean	0.0382	0.0384	2.076	0.716	0.662	2.108	2.332
SD	0.0067	0.0063	0.070	0.080	0.055	0.282	0.756
N	5	5	5	5	5	5	5

> = Out of range

TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
41	0.047	0.052	1.95	0.72	0.75	1.91	1.97
42	0.044	0.044	1.97	0.59	0.61	1.87	1.93
43	0.045	0.039	2.07	0.61	0.61	1.98	2.00
44	0.049	0.050	2.02	0.65	0.62	1.80	NT !
45	0.041	0.034	1.97	0.81	0.73	1.88	1.81
Mean	0.0452	0.0438	1.996	0.676	0.664	1.888	1.928
SD	0.0030	0.0075	0.049	0.090	0.070	0.065	0.083
N	5	5	5	5	5	5	4

! = Result Comment

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
71	0.042	0.041	2.15	0.82	0.81	1.84	1.78
72	0.042	0.034	2.08	0.81	0.74	1.91	1.91
73	0.043	0.046	1.99	0.69	0.72	1.83	1.93
74	0.041	0.039	2.10	0.78	0.80	2.11	2.06
75	0.049	0.052	2.27	0.89	0.97	2.47	2.46
Mean	0.0434	0.0424	2.118	0.798	0.808	2.032	2.028
SD	0.0032	0.0069	0.103	0.073	0.098	0.269	0.261
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
101	0.034	0.034	1.98	0.60	0.58	1.94	1.86
102	0.035	0.027	2.02	0.62	0.64	1.89	1.90
103	0.036	0.031	2.14	0.66	0.55	2.89	3.84 >
104	0.030	0.037	1.78	0.57	0.53	1.78	1.79
105	0.038	0.043	2.06	0.85	0.74	1.90	1.90
Mean	0.0346	0.0344	1.996	0.660	0.608	2.080	2.258
SD	0.0030	0.0061	0.134	0.111	0.085	0.457	0.886
N	5	5	5	5	5	5	5

> = Out of range

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
131	0.038	0.042	2.14	0.79	0.75	2.05	2.00
132	0.037	0.038	2.15	0.79	0.78	1.88	1.90
133	0.039	0.037	2.04	0.83	0.76	1.59	1.62
134	0.038	0.038	2.17	0.93	0.84	2.14	2.14
135	0.045	0.039	1.93	0.70	0.75	2.11	2.17
Mean	0.0394	0.0388	2.086	0.808	0.776	1.954	1.966
SD	0.0032	0.0019	0.101	0.083	0.038	0.227	0.222
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
191	0.039	0.041	2.01	0.60	0.62	1.87	2.01
192	0.034	0.039	1.87	0.77	0.78	2.09	1.90
193	0.030	0.031	1.95	0.69	0.64	1.95	1.96
194	0.032	0.028	2.09	0.63	0.64	1.86	1.92
195	0.039	0.044	2.07	0.86	0.84	2.06	2.03
Mean	0.0348	0.0366	1.998	0.710	0.704	1.966	1.964
SD	0.0041	0.0068	0.090	0.106	0.099	0.106	0.056
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
11	1.26	1.70	1.85	12.0	2.28	0.022	0.022
12	1.29	1.66	1.73	14.6	1.79	0.026	0.022
13	1.38	1.73	1.83	15.6	2.00	0.022	0.021
14	1.21	1.56	1.77	12.5	2.02	0.015	0.032
15	1.24	1.85	1.83	13.5	2.14	0.012	0.029
Mean	1.276	1.700	1.802	13.64	2.046	0.0194	0.0252
SD	0.065	0.106	0.050	1.48	0.182	0.0057	0.0050
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
41	1.27	1.50	1.60	12.2	2.18	0.018	0.034
42	1.23	1.67	1.74	13.6	2.07	0.043	0.035
43	1.31	1.57	1.62	14.8	2.40	0.011	0.019
44	1.31	1.55	1.46	14.2	2.13	0.018	0.034
45	1.30	1.68	1.65	14.6	1.83	0.010	0.023
Mean	1.284	1.594	1.614	13.88	2.122	0.0200	0.0290
SD	0.034	0.078	0.101	1.04	0.205	0.0134	0.0074
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
71	1.36	1.69	1.65	15.7	2.21	0.016	0.055
72	1.30	1.45	1.60	13.5	1.85	0.016	0.037
73	1.27	1.46	1.54	13.1	1.72	0.020	0.044
74	1.42	1.71	1.72	15.0	2.19	0.030	0.049
75	1.54	2.13	1.80	16.1	2.95	0.030	0.035
Mean	1.378	1.688	1.662	14.68	2.184	0.0224	0.0440
SD	0.107	0.276	0.102	1.33	0.478	0.0071	0.0083
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
101	1.24	1.61	1.61	13.6	2.08	0.013	0.016
102	1.24	1.52	1.59	14.2	2.14	0.013	0.026
103	1.48	1.88	1.88	18.5	2.46	0.026	0.055
104	1.31	1.49	1.43	13.8	2.21	0.012	0.016
105	1.33	1.66	1.76	15.2	2.20	0.020	0.028
Mean	1.320	1.632	1.654	15.06	2.218	0.0168	0.0282
SD	0.098	0.154	0.172	2.02	0.145	0.0061	0.0160
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
131	1.32	1.49	1.50	14.2	1.95	0.017	0.049
132	1.23	1.45	1.56	14.0	1.95	0.017	0.043
133	1.26	1.57	1.67	12.8	1.74	0.020	0.053
134	1.48	1.74	1.87	14.6	2.13	0.013	0.032
135	1.22	1.65	1.72	13.5	2.33	0.022	0.057
Mean	1.302	1.580	1.664	13.82	2.020	0.0178	0.0468
SD	0.107	0.118	0.144	0.69	0.222	0.0034	0.0098
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
191	1.36	1.52	1.62	12.3	2.64	0.020	0.041
192	1.20	1.57	1.64	13.1	2.17	0.019	0.058
193	1.43	1.62	1.70	15.5	2.16	0.015	0.037
194	1.11	1.30	1.32	10.5	1.60	0.015	0.021
195	1.47	1.67	1.73	13.8	2.56	0.019	0.026
Mean	1.314	1.536	1.602	13.04	2.226	0.0176	0.0366
SD	0.154	0.143	0.164	1.85	0.413	0.0024	0.0144
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
11	0.012	1.505	0.81	0.53	0.022
12	0.013	1.505	0.83	0.46	0.010
13	0.014	1.222	0.89	0.56	0.010
14	0.010	1.119	0.82	0.68	0.009
15	0.014	1.128	0.74	0.38	0.025
Mean	0.0126	1.2958	0.818	0.522	0.0152
SD	0.0017	0.1952	0.054	0.112	0.0077
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
41	0.014	1.110	0.74	0.40	0.011
42	0.015	1.488	0.89	0.62	0.017
43	0.010	1.400	0.97	0.32	0.017
44	0.013	0.915	0.89	0.59	0.010
45	0.009	1.326	0.93	0.44	0.012
Mean	0.0122	1.2478	0.884	0.474	0.0134
SD	0.0026	0.2328	0.087	0.128	0.0034
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
71	0.012	1.281	1.11	0.45	0.013
72	0.012	0.651	0.91	0.40	0.010
73	0.014	0.991	0.72	0.33	0.009
74	0.013	1.304	0.93	0.57	0.015
75	0.015	1.509	1.03	0.59	0.035
Mean	0.0132	1.1472	0.940	0.468	0.0164
SD	0.0013	0.3332	0.147	0.111	0.0107
N	5	5	5	5	5

TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
101	0.013	1.259	0.80	0.41	0.016
102	0.014	1.706	0.82	0.50	0.022
103	0.015	0.753	1.01	0.53	0.017
104	0.010	1.009	0.90	0.40	0.007
105	0.015	1.539	0.80	0.54	0.012
Mean	0.0134	1.2532	0.866	0.476	0.0148
SD	0.0021	0.3862	0.090	0.067	0.0056
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
131	0.014	1.268	1.05	0.30	0.017
132	0.015	1.114	0.83	0.35	0.018
133	0.014	1.511	0.86	0.53	0.013
134	0.015	1.520	0.99	0.55	0.011
135	0.014	1.063	0.78	0.49	0.016
Mean	0.0144	1.2952	0.902	0.444	0.0150
SD	0.0005	0.2148	0.113	0.112	0.0029
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
191	0.013	1.007	0.84	0.43	0.012
192	0.011	1.462	0.76	0.39	0.011
193	0.014	1.266	0.79	0.56	0.013
194	0.011	0.958	0.85	0.50	0.011
195	0.014	0.636	1.05	0.44	0.012
Mean	0.0126	1.0658	0.858	0.464	0.0118
SD	0.0015	0.3150	0.113	0.067	0.0008
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
26	0.066	0.066	1.79	0.053	0.067	1.01
27	0.058	0.061	1.94	0.074	0.097	0.94
28	0.067	0.062	1.96	0.051	0.055	1.05
29	0.054	0.053	1.88	0.065	0.064	1.01
30	0.051	0.051	2.05	0.057	0.065	0.98
Mean	0.0592	0.0586	1.924	0.0600	0.0696	0.998
SD	0.0071	0.0063	0.097	0.0095	0.0160	0.041
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
56	0.048	0.043	1.84	0.077	0.071	0.97
57	0.042	0.032	1.87	0.041	0.044	0.84
58	0.046	0.043	1.90	0.053	0.052	1.09
59	0.055	0.059	2.01	0.057	0.066	0.94
60	0.048	0.047	1.80	0.057	0.096	0.92
Mean	0.0478	0.0448	1.884	0.0570	0.0658	0.952
SD	0.0047	0.0097	0.080	0.0130	0.0200	0.091
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
86	0.044	0.041	1.88	0.044	0.041	0.92
87	0.054	0.050	1.91	0.086	0.083	0.95
88	0.043	0.045	1.92	0.064	0.061	0.99
89	0.037	0.036	1.86	0.063	0.062	1.02
90	0.041	0.042	1.81	0.037	0.059	0.85
Mean	0.0438	0.0428	1.876	0.0588	0.0612	0.946
SD	0.0063	0.0052	0.044	0.0192	0.0149	0.066
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
116	0.053	0.051	1.91	0.059	0.069	0.97
117	0.042	0.044	1.85	0.055	0.068	0.93
118	0.044	0.041	1.94	0.098	0.083	0.92
119	0.053	0.044	1.93	0.053	0.048	1.06
120	0.046	0.038	1.81	0.051	0.045	0.95
Mean	0.0476	0.0436	1.888	0.0632	0.0626	0.966
SD	0.0051	0.0048	0.056	0.0197	0.0159	0.056
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
146	0.045	0.046	1.92	0.067	0.068	0.90
147	0.049	0.050	2.03	0.075	0.074	1.41
148	0.055	0.053	2.02	0.061	0.062	0.99
149	0.052	0.054	2.02	0.062	0.087	1.11
150	0.053	0.048	1.92	0.068	0.064	1.03
Mean	0.0508	0.0502	1.982	0.0666	0.0710	1.088
SD	0.0039	0.0033	0.057	0.0056	0.0100	0.195
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
206	0.056	0.054	1.82	0.050	0.051	0.96
207	0.049	0.050	1.86	0.046	0.059	1.01
208	0.038	0.046	1.88	0.054	0.046	0.85
209	0.060	0.061	1.91	0.043	0.046	0.97
210	0.044	0.043	1.87	0.063	0.068	1.06
Mean	0.0494	0.0508	1.868	0.0512	0.0540	0.970
SD	0.0089	0.0070	0.033	0.0078	0.0095	0.078
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
26	1.04	1.12	10.2	1.53	0.015	0.026
27	1.16	1.28	10.6	1.68	0.027	0.027
28	1.16	1.23	10.6	1.77	0.015	0.018
29	0.93	0.95	9.1	1.45	0.020	0.048
30	1.04	1.06	9.7	1.45	0.018	0.053
Mean	1.066	1.128	10.04	1.576	0.0190	0.0344
SD	0.097	0.132	0.64	0.143	0.0049	0.0152
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
56	0.97	0.97	8.8	1.72	0.028	0.042
57	1.12	1.12	9.6	1.27	0.016	0.045
58	1.09	1.07	11.5	1.87	0.018	0.039
59	1.01	1.04	9.5	1.54	0.010	0.023
60	1.01	1.13	9.5	1.51	0.018	0.039
Mean	1.040	1.066	9.78	1.582	0.0180	0.0376
SD	0.062	0.065	1.01	0.227	0.0065	0.0085
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
86	0.89	0.92	7.6	1.26	0.013	0.030
87	1.15	1.19	9.2	1.45	0.017	0.053
88	1.11	1.17	9.9	1.40	0.023	0.045
89	1.06	1.16	8.6	1.57	0.022	0.026
90	0.83	0.86	7.7	1.29	0.011	0.015
Mean	1.008	1.060	8.60	1.394	0.0172	0.0338
SD	0.140	0.157	0.98	0.125	0.0053	0.0152
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
116	0.99	1.03	8.9	1.35	0.016	0.038
117	1.00	1.08	8.4	1.21	0.010	0.030
118	1.06	1.13	10.0	1.31	0.024	0.052
119	1.12	1.14	9.1	1.62	0.025	0.052
120	1.08	1.05	9.3	1.20	0.018	0.061
Mean	1.050	1.086	9.14	1.338	0.0186	0.0466
SD	0.055	0.048	0.59	0.170	0.0061	0.0124
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
146	0.89	0.94	8.5	1.38	0.056	0.032
147	1.25	1.34	10.4	1.56	0.018	0.038
148	0.97	1.05	9.4	1.41	0.017	0.034
149	1.12	1.18	11.3	1.78	0.022	0.055
150	1.22	1.27	10.4	1.77	0.019	0.031
Mean	1.090	1.156	10.00	1.580	0.0264	0.0380
SD	0.156	0.162	1.07	0.191	0.0167	0.0099
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
206	0.97	1.04	8.6	1.37	0.020	0.051
207	1.07	1.10	9.4	1.41	0.011	0.052
208	0.85	1.02	8.3	1.32	0.010	0.014
209	1.23	1.26	9.9	1.38	0.023	0.025
210	1.10	1.12	10.4	1.54	0.011	0.027
Mean	1.044	1.108	9.32	1.404	0.0150	0.0338
SD	0.143	0.094	0.88	0.083	0.0060	0.0169
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
26	0.016	0.77	0.62	0.015
27	0.017	0.62	0.58	0.013
28	0.019	0.86	0.52	0.014
29	0.020	0.62	0.46	0.018
30	0.015	0.69	0.37	0.018
Mean	0.0174	0.712	0.510	0.0156
SD	0.0021	0.103	0.099	0.0023
N	5	5	5	5

TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
56	0.018	0.67	0.38	0.019
57	0.015	0.55	0.40	0.012
58	0.016	0.78	0.51	0.014
59	0.017	0.56	0.49	0.019
60	0.018	0.66	0.33	0.010
Mean	0.0168	0.644	0.422	0.0148
SD	0.0013	0.094	0.076	0.0041
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
86	0.011	0.59	0.33	0.011
87	0.017	0.59	0.66	0.016
88	0.017	0.63	0.44	0.010
89	0.014	0.63	0.41	0.008
90	0.012	0.58	0.41	0.014
Mean	0.0142	0.604	0.450	0.0118
SD	0.0028	0.024	0.124	0.0032
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
116	0.014	0.55	0.38	0.012
117	0.010	0.55	0.38	0.009
118	0.017	0.70	0.52	0.015
119	0.016	0.57	0.41	0.014
120	0.017	0.58	0.32	0.014
Mean	0.0148	0.590	0.402	0.0128
SD	0.0029	0.063	0.074	0.0024
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
146	0.012	0.67	0.40	0.011
147	0.018	0.79	0.42	0.010
148	0.018	0.65	0.46	0.013
149	0.014	0.87	0.63	0.013
150	0.016	0.69	0.52	0.009
Mean	0.0156	0.734	0.486	0.0112
SD	0.0026	0.093	0.093	0.0018
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
206	0.013	0.66	0.44	0.012
207	0.020	0.68	0.39	0.015
208	0.017	0.56	0.26	0.008
209	0.015	0.73	0.47	0.008
210	0.016	0.74	0.45	0.010
Mean	0.0162	0.674	0.402	0.0106
SD	0.0026	0.072	0.085	0.0030
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	5	Male	129	Prostate Gland	Replacement	NT
			Comment:	Not taken at necropsy			

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	5	Female	144	Spleen Weight	Replacement	NT
			Comment:	Not taken at necropsy			

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	38	1	Male	15	Testis - Right	Out of Range	>
	38	2	Male	44	Testis - Right	Replacement	NT
			Comment:	Not taken at necropsy			
	38	4	Male	103	Testis - Right	Out of Range	>

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6. HISTOPATHOLOGY REPORT

HISTOPATHOLOGY REPORT

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

LPT Project No.38166

27 June 2020

Veterinary Pathologist:

s 22

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HISTOPATHOLOGY REPORT

Repeat-Dose Toxicity Study of
Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins by Repeated
Intramuscular Administration
to Wistar Han Rats

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HISTOPATHOLOGY REPORT

PAGE: 1
LPT Study No. 38166

Repeat-Dose Toxicity Study of
Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins by Repeated
Intramuscular Administration
to Wistar Han Rats

AUTHENTICATION

The undersigned hereby declares that the histopathology data in this report were compiled by him, and that they reflect accurately the primary data records.

27 June 2020
Date

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PRINCIPAL SECTION

METHODS

Group design for the histopathological evaluation

Text table 1: Group size and dose levels for the histopathological evaluation

Group	Dose level [µg/animal] (Test item / Control)	Number and sex of animals MS + RP	Animal no.	
			MS	RP
1	0 (Buffer) Control	10 + 5 m 10 + 5 f	1 - 10 16 - 25	11 - 15 26 - 30
2	30 (LNP uRNA RBD) BNT162a1	10 + 5 m 10 + 5 f	31 - 40 46 - 55	41 - 45 56 - 60
3	10 (LNP uRNA RBD) BNT162a1	10 + 5 m 10 + 5 f	61 - 70 76 - 85	71 - 75 86 - 90
4	30 (LNP modRNA RBD) BNT162b1	10 + 5 m 10 + 5 f	91 - 100 106 - 115	101 - 105 116 - 120
5	100 (LNP modRNA RBD) BNT162b1	10 + 5 m 10 + 5 f	121 - 130 136 - 145	131 - 135 146 - 150
6	30 (LNP saRNA RBD) BNT162c1	10 + 5 m 10 + 5 f	151 - 160 166 - 175	161 - 165 176 - 180
7	100 (LNP modRNA Sp2) BNT162b2	10 + 5 m 10 + 5 f	181 - 190 196 - 205	191 - 195 206 - 210

MS: Main study
RP: Recovery period
m: male
f: female

The organs listed in section 3.8.10.2 of the main report of all animals of groups 1 to 7 were examined histologically after preparation of paraffin sections and haematoxylin-eosin staining.

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The stained sections from all animals examined were prepared and provided by **LPT**, Hamburg. The macroscopic findings were recorded and provided by **LPT**, Hamburg.

Data compilation

The animal data and macroscopic observations were derived from descriptions recorded by **LPT**, Hamburg, during the post mortem examination of each animal. The histopathological findings of the undersigned pathologist were recorded and calendared using the departmental computerized systems (Provantis® Integrated preclinical software, version 10.2.1, Instem LSS Ltd., United Kingdom).

The histopathological findings recorded in the organs/tissues are summarised in the tables 'Microscopic Findings by Incident' and 'Microscopic Findings by Severity'.

The 'Microscopic Findings by Incident' table lists the frequency of observations per group and sex as percentage of the affected animals per group.

The 'Microscopic Findings by Severity' table lists the severity of observations per group and sex (for severity grading see section 'Explanation of Codes and Symbols').

The 'Tabulated Animal Data' table lists the severity of observations for individual animals.

The 'Individual Animal Data' table comprises the animal data, the macroscopic observations and all microscopic observations of each animal.

The slides were evaluated in April, May and June 2020.

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RESULTS AND CONCLUSION

Mortality

Main study / Recovery period

None of the male and female animals of groups 1 to 7 died or had to be sacrificed prematurely.

Macroscopic findings

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Terminal sacrifice

Test item-related macroscopic findings at the end of dosing included injection site findings and increased spleen and draining lymph node (iliac) size. Increased spleen size correlated with increased absolute spleen weights and spleen:body weight ratios.

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Text table 1: Incidences of test item-related macroscopic findings for the animals treated with BNT162a1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened / indurated / (skin) incrusted	3/10	1/10	5/10	5/10
Injection site I (left):				
- Muscle(s) indurated / muscles thickened / indurated	7/10	8/10	10/10	10/10
Spleen:				
- Enlarged	5/10	2/10	2/10	4/10
Lymph node (iliac):				
- Enlarged	4/10	3/10	1/10	1/10

.../... number of animals affected per number of animals examined

Text table 2: Incidences of test item-related macroscopic findings for the animals treated with BNT162b1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened	0/10	0/10	1/10	1/10
Injection site I and/or II (left/right):				
- Muscle(s) indurated / muscles thickened / indurated / enlarged	7/10	6/10	7/10	6/10
Spleen:				
- Enlarged	1/10	1/10	5/10	7/10
Lymph node (iliac or renal, left):				
- Enlarged	6/10	4/10	7/10	8/10

.../... number of animals affected per number of animals examined

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Text table 3: Incidences of test item-related macroscopic findings for the animals treated with BNT162c1 or BNT162b2

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 10 (group 6) or test day 17 (group 7)				
Organ / Finding	**BNT162c1**		**BNT162b2**	
	Group 6: 30 µg/animal		**Group 7: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened and/or incrusted	9/10	9/10	1/10	1/10
Injection site I and/or II (left/right):				
- Muscle(s) indurated or jellied / thickened / indurated / enlarged	10/10	10/10	7/10	9/10
Spleen:				
- Enlarged	5/10	1/10	2/10	7/10
Lymph node (iliac or iliac/renal):				
- Enlarged	1/10	2/10	5/10	6/10
Sciatic nerve (left):				
- adhered to injection site I	0/10	0/10	0/10	3/10

.../... number of animals affected per number of animals examined

Recovery sacrifice

All macroscopic findings noted at the injection sites and for the spleen had subsided in all animals of all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups)

Enlarged iliac lymph nodes were still noted for a few animals as follows:

Group 4 (30 µg BNT162b1/animal): One of 5 females
Group 5 (100 µg BNT162b1/animal): All 5 males, 2 of 5 females
Group 7 (100 µg BNT162b2/animal): One of 5 males, 3 of 5 females

These findings are regarded to be related to the previous test item treatment.

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Further findings in form of emphysematous lungs, a reddened thymus, an enlarged right testis, a dilated uterus, in some cases filled with clear liquid, a prostate and seminal vesicles that were reduced in size, and enlarged adrenals were noted for individual male and female animals in the test item-treated groups and the control group at terminal sacrifice or at recovery sacrifice. Due to the isolated occurrence per finding, all of these findings are considered as spontaneous changes that are not test item-related.

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Microscopic findings

Terminal sacrifice

Test item-related microscopic findings at the end of dosing included inflammation at the injection site and surrounding tissues, increased cellularity of germinal centers and increased plasma cells in the draining (iliac) lymph node, increased cellularity (hematopoiesis) in the bone marrow and spleen, and vacuolation of hepatocytes in the portal regions. All microscopic findings were partially or fully recovered at the end of the 3 week recovery phase.

Test item-related injection site reactions were present in all groups and characterized by mostly moderate inflammation (up to marked) in males and moderate inflammation in females. The most severe findings were noted consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate edema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. Injection site findings were partially recovered at the end of the 3-week recovery phase. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac). These findings were mostly recovered at the end of the 3-week recovery phase.

Test item-related findings in the draining (iliac) lymph node were characterized by increased cellularity of the follicular germinal centers and increased plasma cells (plasmacytosis) and were variably present in all groups.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen were present in all groups.

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A test item-related vacuolation of hepatocytes in the portal regions of the liver was present in all groups.

A few minor microscopic changes were recorded for the organs examined in this study. The type, incidence and severity of all microscopic findings observed did not indicate any relationship to the treatment with the test item. All changes are regarded to be spontaneous in nature being within the normal background pathology commonly seen in rats of this strain and age.

Test item-related findings were noted for all test items and all dose levels in male and female animals as given in the text tables following on the next pages.

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Text table 4: Incidences of test item-related microscopic findings for the animals treated with BNT162a1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site l (left):				
- Fibrosis intramuscular/interstitial	10/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	10/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	9/10**	9/10**	9/10**
- Edema, subcutis	10/10**	9/10**	6/10*	10/10**
- Edema intramuscular/interstitial	7/10**	8/10**	2/10	10/10**
- Edema inter-/ perimuscular	10/10**	10/10**	7/10**	10/10**
- Hyperplasia, epidermis	9/10**	7/10**	10/10**	9/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	1/10	3/10	0/10
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	1/10	0/10	1/10
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	3/10	0/10	0/10
Lymph node (iliac):				
- Plasmacytosis	7/10**	7/10**	5/10*	3/10
- Inflammation	0/10	3/10	5/10*	6/10*
- Increased cellularity, germinal center	9/10	10/10**	9/10	8/10
Spleen:				
- Increased haematopoiesis	3/10	2/10	0/10	0/10
Liver				
- Vacuolation, hepatocellular, periportal	1/10	6/10*	1/10	10/10**

.../... number of animals affected per number of animals examined
* significantly different from control ($p \leq 0.05$)
** significantly different from control ($p \leq 0.01$)

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Text table 5: Incidences of test item-related microscopic findings for the animals treated with BNT162b1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	10/10**	10/10**	10/10**
- Edema, subcutis	9/10**	10/10**	10/10**	10/10**
- Edema intramuscular/interstitial	8/10**	9/10**	10/10**	10/10**
- Edema inter-/ perimuscular	10/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	8/10**	10/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	1/10	4/10	7/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	4/10	6/10*
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	0/10	2/10	1/10
Lymph node (iliac):				
- Plasmacytosis	9/10**	8/10**	8/10**	10/10**
- Inflammation	0/10	0/10	5/10*	8/9**
- Increased cellularity, geminal center	10/10	8/10	10/10	10/10**
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	7/10**
Liver				
- Vacuolation, hepatocellular, periportal	0/10	10/10**	8/10**	10/10**

.../... number of animals affected per number of animals examined
* significantly different from control ($p \leq 0.05$)
** significantly different from control ($p \leq 0.01$)

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Text table 6: Incidences of test item-related microscopic findings for the animals treated with BNT162c1 and BNT162b2

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 10 (group 6) or test day 17 (group 7)				
Organ / Finding	**BNT162c1**		**BNT162b2**	
	Group 6: 30 µg/animal		**Group 7: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed	9/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	8/10**	9/10**	10/10**	10/10**
- Edema, subcutis	9/10**	10/10**	10/10**	10/10**
- Edema intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Edema inter-/ perimuscular	9/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	10/10**	9/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	0/10	10/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	2/10	9/10**
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	4/10	2/10	0/10
Lymph node (iliac):				
- Plasmacytosis	6/10*	7/10**	10/10**	10/10**
- Inflammation	4/10	7/10**	9/10**	6/10*
- Increased cellularity, germinal center	10/10	10/10**	10/10	10/10**
Skeletal muscle:				
- Infiltration, lymphohistiogranulocyt.	0/10	0/10	5/10*	0/10
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	8/10**
Liver				
- Vacuolation, hepatocellular, periportal	1/10	10/10**	9/10**	10/10**

.../... number of animals affected per number of animals examined
* significantly different from control ($p \leq 0.05$)
** significantly different from control ($p \leq 0.01$)

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Recovery sacrifice

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland; skeletal muscle) and spleen had subsided in all animals of all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups). Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen were fully recovered at the end of the 3-week recovery phase.

Test item-related vacuolation of hepatocytes in the portal regions of the liver was fully recovered at the end of the 3-week recovery phase.

The incidence and the severity of the remaining findings were markedly reduced compared to the main study animals.

The infiltration of macrophages in the iliac lymph nodes of previously treated recovery animals were regarded as consequence of phagocytosis relating to the inflammatory reactions at the injection sites.

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Discussion synopsis

Injection site inflammation, as well as inflammation in the adjacent tissues, was an anticipated response to an immune response to the administered test article. Inflammation was generally most severe in animals administered **100 µg** of either **BNT162b1** or **BNT162b2/animal** at the end of dosing, followed by **30 µg BNT162a1/animal**. Ulceration at the injection site was present only in rats administered **BNT162a1**. The inflammation was partially or fully resolved at the end of the recovery phase, indicating reversibility.

Increased cellularity of the germinal centers of the draining (iliac) lymph node and plasmacytosis is consistent with the anticipated immune activation by the test articles and inflammation at the injection site.

Increases in bone marrow cellularity (increased hematopoiesis) and extramedullary hematopoiesis in the spleen are consistent with a response to inflammation and immune responses induced by the test article.

Test item-related vacuolation of portal hepatocytes was present in all groups. The vacuolation was unassociated with markers of hepatocyte damage (i.e. ALAT, ASAT) and has been reported in animals administered pegylated compounds. The findings were fully reversed at the end of the recovery phase.

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EXPLANATION OF CODES AND SYMBOLS

Tissue Result

N	tissue within normal histological limits
.	not recorded
+	tissue observation present
X	not examined

Grade

.	not recorded
1	minimal
2	mild
3	moderate
4	marked
#	different severities recorded, e.g. for the two parts of a paired organ
P	present - no grade or classification

Symbols

%	per cent
*	statistically significant (at $p \leq 0.05$, exact test of R. A. FISHER)
**	statistically significant (at $p \leq 0.01$, exact test of R. A. FISHER)
TGL	trackable gross lesion

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TABLES

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
ADRENAL GLAND, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	73.3%	66.7%	73.3%	80.0%	86.7%	73.3%	80.0%	80.0%	60.0%	80.0%	93.3%	86.7%	80.0%
Dilation; vascular	13.3%	26.7%	33.3%	26.7%	20.0%	13.3%	20.0%	20.0%	20.0%	33.3%	20.0%	6.7%	13.3%	20.0%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	80.0%	80.0%	100.0%	80.0%	86.7%	73.3%	86.7%	86.7%	86.7%	86.7%	86.7%	100.0%	93.3%
Dilation; vascular	13.3%	20.0%	20.0%	0.0%	20.0%	13.3%	20.0%	13.3%	13.3%	6.7%	13.3%	13.3%	0.0%	6.7%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
AORTA ABDOMINALIS;														
Examined	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	66.7%	100.0%	86.7%	100.0%	93.3%	93.3%	100.0%	53.3%	100.0%	40.0%
Inflammation; mixed; surrounding tissue	0.0%	0.0%	0.0%	0.0%	26.7%	0.0%	13.3%	0.0%	6.7%	6.7%	0.0%	40.0%	0.0%	60.0%
Infiltration, Lymphocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
BONE MARROW, OS FEMORIS WITH JOINT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%	100.0%	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%
Increased Cellularity	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
BONE, STERNUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	93.3%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; muscle	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
BRAIN, BRAIN STEM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(14)
Within Normal Limits	-	-	-	-	-	-	-	80.0%	53.3%	66.7%	66.7%	73.3%	66.7%	78.6%
Keratinization; epithelial	-	-	-	-	-	-	-	20.0%	46.7%	33.3%	33.3%	26.7%	33.3%	21.4%
Cyst; keratinized	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
EPIDIDYMIS, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	26.7%	13.3%	13.3%	53.3%	33.3%	33.3%	26.7%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	73.3%	86.7%	86.7%	46.7%	66.7%	66.7%	73.3%	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	33.3%	13.3%	20.0%	33.3%	26.7%	26.7%	13.3%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	66.7%	86.7%	80.0%	60.0%	73.3%	73.3%	86.7%	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
EPIDIDYMIS, RIGHT; (continued)														
Infiltration; mixed	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Oligospermia	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
ESOPHAGUS;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EYE, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	93.3%	100.0%	100.0%	86.7%	93.3%	100.0%	93.3%	93.3%	80.0%	73.3%	73.3%	86.7%	73.3%	93.3%
Infiltration, Lymphocytic	6.7%	0.0%	0.0%	13.3%	6.7%	0.0%	0.0%	0.0%	13.3%	0.0%	13.3%	6.7%	6.7%	6.7%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	6.7%	6.7%	6.7%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	6.7%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
HARDERIAN GLAND, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	93.3%	93.3%	100.0%	86.7%	80.0%	100.0%	93.3%	93.3%	86.7%	100.0%	100.0%	93.3%	73.3%
Infiltration, Lymphocytic	13.3%	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	6.7%	26.7%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
HARDERIAN GLAND, RIGHT; (continued)														
Inflammation, Chronic	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	80.0%	86.7%	80.0%	93.3%	100.0%	86.7%	100.0%	86.7%	93.3%	93.3%	93.3%	93.3%	100.0%
Infiltration; lymphohistiocytic	0.0%	6.7%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	13.3%	6.7%	6.7%	6.7%	0.0%	13.3%	0.0%	6.7%	6.7%	0.0%	6.7%	6.7%	0.0%
INJECTION SITE I;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	60.0%	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%
Fibrosis; intramuscular / interstitial	0.0%	66.7%	86.7%	86.7%	86.7%	60.0%	93.3%	0.0%	86.7%	73.3%	93.3%	73.3%	66.7%	93.3%
Fibrosis; inter- / perimuscular	0.0%	100.0%	100.0%	93.3%	100.0%	66.7%	100.0%	0.0%	100.0%	100.0%	100.0%	100.0%	93.3%	93.3%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%
Hemorrhage; subcutis	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	13.3%	13.3%	33.3%	26.7%	0.0%	20.0%	0.0%	26.7%	6.7%	26.7%	6.7%	0.0%	26.7%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	33.3%	26.7%	33.3%	33.3%	6.7%	33.3%	0.0%	26.7%	20.0%	33.3%	26.7%	20.0%	26.7%
Inflammation; neutrophilic; dermis; epidermis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Inflammation; plasmacytic; perivascular	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; vascular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Inflammation; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	66.7%	66.7%	66.7%	66.7%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
Inflammation; mixed; intramuscular / interstitial	0.0%	60.0%	66.7%	66.7%	60.0%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
INJECTION SITE I; (continued)														
Inflammation; mixed; inter- / perimuscular	0.0%	66.7%	66.7%	66.7%	66.7%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
Mineralization; inter- / perimuscular	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
Necrosis; dermis; subcutis	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermis	0.0%	13.3%	13.3%	0.0%	0.0%	6.7%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	13.3%	13.3%
Degeneration; myofiber	6.7%	60.0%	60.0%	60.0%	66.7%	53.3%	66.7%	0.0%	60.0%	60.0%	66.7%	66.7%	60.0%	66.7%
Regeneration; muscle	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Material; hair	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	40.0%	66.7%	60.0%	53.3%	60.0%	66.7%	0.0%	66.7%	60.0%	66.7%	66.7%	66.7%	66.7%
Edema; intramuscular / interstitial	0.0%	13.3%	46.7%	53.3%	53.3%	60.0%	66.7%	0.0%	66.7%	53.3%	60.0%	66.7%	66.7%	66.7%
Edema; inter- / perimuscular	0.0%	46.7%	66.7%	66.7%	53.3%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
Hyperkeratosis; epidermal	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	60.0%	60.0%	60.0%	66.7%	60.0%	60.0%	0.0%	60.0%	46.7%	53.3%	66.7%	66.7%	66.7%
Scab; epidermal	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	6.7%	6.7%
Pustule; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Multinucleated Macrophages; inter- / perimuscular	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;														
Examined	(15)	(5)	(0)	(0)	(15)	(0)	(15)	(15)	(1)	(0)	(0)	(15)	(0)	(15)
Within Normal Limits	66.7%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%
Degeneration; myofiber	0.0%	60.0%	0.0%	0.0%	66.7%	0.0%	66.7%	6.7%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Regeneration; muscle	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	46.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	60.0%
Scab; epidermal	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	60.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Edema; inter- / perimuscular	0.0%	40.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Edema; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Necrosis; myofiber	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Necrosis; dermis; subcutis	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; traumatic; myofiber	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; inter- / perimuscular	0.0%	60.0%	0.0%	0.0%	100.0%	0.0%	100.0%	0.0%	100.0%	0.0%	0.0%	93.3%	0.0%	93.3%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
INJECTION SITE II; (continued)														
Fibrosis; intramuscular / interstitial ..	0.0%	60.0%	0.0%	0.0%	93.3%	0.0%	86.7%	0.0%	0.0%	0.0%	0.0%	80.0%	0.0%	80.0%
Fibrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermal	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	26.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	26.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%	33.3%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	26.7%
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%	26.7%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	20.0%
Inflammation; mixed	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Inflammation; mixed; inter- / perimuscular	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Inflammation; mixed; intramuscular / interstitial	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
INTESTINE, CECUM;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	93.3%	93.3%	100.0%	86.7%	80.0%	100.0%	100.0%	100.0%	93.3%	86.7%	80.0%	86.7%	100.0%	93.3%
Hyperplasia; mucosa-associated lymphoid tissue	6.7%	6.7%	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	6.7%	13.3%	6.7%	0.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased ...	0.0%	0.0%	0.0%	6.7%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	13.3%	0.0%	6.7%
INTESTINE, COLON;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	93.3%	93.3%	60.0%	86.7%	66.7%	80.0%	100.0%	100.0%	100.0%	80.0%	86.7%	86.7%	73.3%	86.7%
Hyperplasia; mucosa-associated lymphoid tissue	6.7%	6.7%	40.0%	13.3%	20.0%	20.0%	0.0%	0.0%	0.0%	20.0%	13.3%	6.7%	26.7%	0.0%
Infiltration, Eosinophilic; increased ...	0.0%	0.0%	0.0%	6.7%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	6.7%	0.0%	13.3%
INTESTINE, DUODENUM;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
INTESTINE, ILEUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	80.0%	73.3%	86.7%	60.0%	93.3%	86.7%	80.0%	80.0%	93.3%	60.0%	86.7%	93.3%	46.7%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	13.3%	26.7%	0.0%	0.0%	6.7%	0.0%	0.0%	33.3%	13.3%	0.0%	40.0%
Hyperplasia; mucosa-associated lymphoid tissue	13.3%	20.0%	26.7%	0.0%	20.0%	6.7%	13.3%	6.7%	20.0%	6.7%	6.7%	6.7%	6.7%	13.3%
Nematodiasis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Congestion	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%
Basophilia; tubule	13.3%	6.7%	6.7%	13.3%	6.7%	20.0%	13.3%	13.3%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%
Infiltration, Lymphocytic	26.7%	6.7%	26.7%	20.0%	6.7%	0.0%	20.0%	6.7%	13.3%	6.7%	6.7%	13.3%	6.7%	0.0%
Mineralization	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	6.7%
Cyst; tubular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	13.3%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%
Degeneration; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	6.7%	6.7%	6.7%	13.3%	26.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	6.7%	6.7%	20.0%	6.7%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%
Inflammation; purulent; pelvis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
KIDNEY, RIGHT; (continued)														
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	6.7%	13.3%	6.7%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	13.3%
Dilation; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; subcapsular	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pyelonephritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	93.3%	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hematopoiesis; extramedullary	13.3%	26.7%	13.3%	20.0%	6.7%	6.7%	13.3%	20.0%	20.0%	6.7%	46.7%	33.3%	40.0%	33.3%
Infiltration; mixed	6.7%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	6.7%
Necrosis	6.7%	0.0%	0.0%	13.3%	0.0%	13.3%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	60.0%	33.3%	66.7%	53.3%	40.0%	13.3%	33.3%	60.0%	26.7%	46.7%	40.0%	13.3%	33.3%	13.3%
Vacuolation; hepatocellular	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; hepatocellular; periportal	6.7%	6.7%	6.7%	0.0%	53.3%	6.7%	60.0%	0.0%	66.7%	40.0%	66.7%	66.7%	73.3%	66.7%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; kupffer cell	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LUNGS WITH BRONCHI;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	20.0%	26.7%	40.0%	20.0%	33.3%	33.3%	46.7%	73.3%	53.3%	60.0%	33.3%	40.0%	66.7%	26.7%
Ossification	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
LUNGS WITH BRONCHI; (continued)														
Hemorrhage; acute	26.7%	20.0%	33.3%	33.3%	20.0%	26.7%	33.3%	6.7%	13.3%	13.3%	6.7%	6.7%	6.7%	0.0%
Hyperplasia; bronchial-associated lymphoid tissue	46.7%	60.0%	33.3%	60.0%	40.0%	40.0%	20.0%	13.3%	26.7%	26.7%	46.7%	26.7%	33.3%	33.3%
Infiltration, Eosinophilic; perivascular	20.0%	6.7%	6.7%	13.3%	20.0%	6.7%	6.7%	6.7%	0.0%	13.3%	26.7%	13.3%	0.0%	53.3%
Infiltration; macrophage; alveolus	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%
Pigmentation; brown; macrophage	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
LYMPH NODE, CERVICAL;														
Examined	(13)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	93.3%	86.7%	100.0%	93.3%	86.7%	93.3%	86.7%	100.0%	93.3%	100.0%	86.7%	92.9%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	6.7%	0.0%
Hemorrhage	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	86.7%	100.0%	100.0%	93.3%	100.0%	100.0%	85.7%
LYMPH NODE, ILIAC;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(14)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	93.3%	100.0%	93.3%	100.0%	93.3%	93.3%	93.3%	93.3%	73.3%	66.7%	100.0%	100.0%	92.9%
Plasmacytosis	0.0%	33.3%	46.7%	73.3%	73.3%	40.0%	73.3%	0.0%	40.0%	66.7%	73.3%	100.0%	53.3%	100.0%
Infiltration, Eosinophilic	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation	0.0%	33.3%	0.0%	0.0%	33.3%	26.7%	60.0%	0.0%	40.0%	20.0%	0.0%	50.0%	46.7%	42.9%
Infiltration; macrophage	0.0%	0.0%	6.7%	6.7%	33.3%	20.0%	33.3%	0.0%	20.0%	0.0%	20.0%	35.7%	33.3%	28.6%
Increased Cellularity; germinal center	86.7%	93.3%	93.3%	100.0%	100.0%	100.0%	100.0%	46.7%	86.7%	100.0%	86.7%	100.0%	93.3%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
LYMPH NODE, MESENTERIC;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	92.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
Pigmentation; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Increased Cellularity; germinal center	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	93.3%	86.7%
LYMPH NODE, RENAL;														
Examined	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
MAMMARY GLANDS;														
Examined	(14)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	86.7%	73.3%	100.0%	100.0%	100.0%	80.0%	100.0%	93.3%	80.0%	100.0%
Inflammation; mixed; interstitium	0.0%	0.0%	0.0%	0.0%	13.3%	20.0%	0.0%	0.0%	0.0%	20.0%	0.0%	6.7%	20.0%	0.0%
Inflammation; mixed; interstitium; lymphatic	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SKELETAL MUSCLE;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	66.7%	93.3%	93.3%	93.3%	100.0%	80.0%	100.0%	93.3%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	33.3%	0.0%	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
NERVE, SCIATIC;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	100.0%	80.0%	100.0%	93.3%	53.3%	100.0%	20.0%	100.0%	100.0%	86.7%	73.3%	26.7%	100.0%	26.7%
Inflammation; perineural	0.0%	20.0%	0.0%	6.7%	46.7%	0.0%	80.0%	0.0%	0.0%	6.7%	26.7%	73.3%	0.0%	73.3%
Vacuolation	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(14)	(15)	(15)	(15)
Within Normal Limits	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	86.7%	86.7%	100.0%	100.0%	93.3%	93.3%
Not Examined: INSUFFICIENT TISSUE TO EVALUATE	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	6.7%	6.7%
Pigmentation; brown; macrophage	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, RIGHT;														
Examined	(15)	(12)	(15)	(14)	(15)	(15)	(14)	(15)	(14)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	91.7%	93.3%	92.9%	100.0%	100.0%	100.0%	100.0%	92.9%	93.3%	93.3%	100.0%	93.3%	100.0%
Pigmentation; brown; macrophage	0.0%	8.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	6.7%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
OVARY, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVARY, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(14)	(15)	(15)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
OVIDUCT, LEFT; (continued)														
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(14)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PANCREAS;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	93.3%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	93.3%	86.7%	100.0%	100.0%	100.0%
Not Examined: NOT PRESENT	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Atrophy; acinar cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Hyperplasia; acinar cell	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%
PARATHYROID, LEFT;														
Examined	(8)	(12)	(11)	(7)	(14)	(12)	(11)	(14)	(15)	(7)	(13)	(10)	(14)	(9)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	90.0%	100.0%	88.9%
Fibrosis; interstitial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	10.0%	0.0%	11.1%
PARATHYROID, RIGHT;														
Examined	(13)	(10)	(11)	(8)	(11)	(12)	(12)	(12)	(15)	(10)	(13)	(8)	(12)	(11)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;														
Examined	(12)	(9)	(13)	(14)	(15)	(14)	(12)	(15)	(11)	(13)	(13)	(12)	(11)	(14)
Within Normal Limits	8.3%	11.1%	0.0%	0.0%	6.7%	7.1%	0.0%	0.0%	0.0%	7.7%	15.4%	0.0%	0.0%	7.1%
Not Examined: NOT PRESENT	25.0%	66.7%	15.4%	7.1%	0.0%	7.1%	25.0%	0.0%	36.4%	15.4%	15.4%	25.0%	36.4%	7.1%
Mineralization	8.3%	11.1%	15.4%	7.1%	0.0%	14.3%	8.3%	0.0%	0.0%	7.7%	0.0%	8.3%	9.1%	7.1%
Inflammation, Granulomatous; follicular	8.3%	0.0%	7.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.7%	7.7%	8.3%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
PEYERS PATCHES; (continued)														
Increased Cellularity; germinal center ..	91.7%	88.9%	100.0%	100.0%	93.3%	92.9%	100.0%	100.0%	100.0%	92.3%	84.6%	100.0%	100.0%	92.9%
PITUITARY GLAND;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)
Within Normal Limits	93.3%	86.7%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	93.3%	93.3%	100.0%	100.0%	93.3%	100.0%
Cyst; pars distalis	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%
Cyst; pars intermedia	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
PROSTATE GLAND;														
Examined	(15)	(14)	(15)	(15)	(14)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	80.0%	85.7%	66.7%	60.0%	85.7%	73.3%	86.7%	-	-	-	-	-	-	-
Infiltration; mixed	0.0%	7.1%	6.7%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Inflammation; purulent	6.7%	0.0%	0.0%	6.7%	7.1%	13.3%	0.0%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	13.3%	7.1%	26.7%	26.7%	7.1%	13.3%	13.3%	-	-	-	-	-	-	-
SALIVARY GLANDS, MANDIBULAR;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(14)	(15)	(15)	(14)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;														
Examined	(15)	(15)	(14)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SEMINAL VESICLES;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
SEMINAL VESICLES; (continued)														
Within Normal Limits	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	-	-	-	-	-	-	-
Infiltration; mixed; surrounding tissue; fat	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
SKIN;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	60.0%
Infiltration; mixed; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	40.0%
Infiltration; mixed; subcutaneous	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SPINAL CORD;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
SPLEEN;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	20.0%	6.7%	53.3%	26.7%	33.3%	53.3%	53.3%	20.0%	20.0%	46.7%	20.0%	40.0%	20.0%	13.3%
Congestion	80.0%	93.3%	40.0%	73.3%	53.3%	46.7%	40.0%	80.0%	80.0%	46.7%	80.0%	40.0%	80.0%	66.7%
Hematopoiesis; increased	0.0%	0.0%	20.0%	0.0%	13.3%	0.0%	13.3%	0.0%	0.0%	13.3%	0.0%	46.7%	0.0%	53.3%
STOMACH, GLANDULAR;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	6.7%	0.0%	33.3%	13.3%	6.7%	33.3%	0.0%	6.7%	20.0%	40.0%	0.0%	0.0%	46.7%	20.0%
Infiltration, Eosinophilic	93.3%	93.3%	60.0%	86.7%	93.3%	60.0%	93.3%	93.3%	66.7%	53.3%	100.0%	100.0%	46.7%	73.3%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Dilation; glandular	0.0%	13.3%	13.3%	6.7%	6.7%	6.7%	6.7%	0.0%	6.7%	13.3%	6.7%	6.7%	6.7%	13.3%
Cyst	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; chief cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	13.3%	0.0%	6.7%	6.7%	0.0%	6.7%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
STOMACH, GLANDULAR; (continued)														
Infiltration, Neutrophilic; mucosa	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
STOMACH, NONGLANDULAR;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits.....	86.7%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	-	-	-	-	-	-	-
Spermatid Giant Cells	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Dilation; tubular	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
TESTIS, RIGHT;														
Examined.....	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits.....	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	-	-	-	-	-	-	-
Not Examined: NOT PRESENT	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Dilation; tubular	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Infiltration; lymphoplasmacytic	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Spermatocoele	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
THYMUS;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	66.7%	46.7%	46.7%	60.0%	60.0%	46.7%	53.3%	46.7%	33.3%	80.0%	60.0%	66.7%	53.3%	40.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Hemorrhage; acute	33.3%	53.3%	53.3%	40.0%	40.0%	53.3%	46.7%	53.3%	66.7%	20.0%	40.0%	33.3%	40.0%	60.0%
THYROID, LEFT;														
Examined.....	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)
Within Normal Limits.....	86.7%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	80.0%	92.9%	100.0%	93.3%	100.0%	100.0%
Cyst; keratinized	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	20.0%	7.1%	0.0%	6.7%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
THYROID, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	93.3%	86.7%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	85.7%	100.0%
Cyst; keratinized	6.7%	13.3%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	14.3%	0.0%
TONGUE;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	93.3%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	93.3%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Granuloma	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Granuloma; hair	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	66.7%	93.3%	80.0%	80.0%	86.7%	100.0%	100.0%	86.7%	86.7%	86.7%	80.0%	93.3%	93.3%	93.3%
Infiltration; lymphohistiocytic	20.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	6.7%	0.0%	13.3%	13.3%	13.3%	0.0%	0.0%	13.3%	0.0%	6.7%	20.0%	6.7%	0.0%	0.0%
Pigmentation; brown; macrophage	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	6.7%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	6.7%
URINARY BLADDER;														
Examined	(15)	(14)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)
Within Normal Limits	100.0%	100.0%	93.3%	92.9%	100.0%	100.0%	100.0%	86.7%	100.0%	100.0%	100.0%	92.9%	100.0%	93.3%
Infiltration, Lymphocytic	0.0%	0.0%	6.7%	7.1%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	7.1%	0.0%	6.7%
UTERUS;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	80.0%	66.7%	86.7%	93.3%	100.0%	93.3%
Dilation	-	-	-	-	-	-	-	0.0%	20.0%	33.3%	13.3%	6.7%	0.0%	6.7%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
VAGINA;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	73.3%	46.7%	53.3%	66.7%	60.0%	60.0%	60.0%
Keratinization; epithelial	-	-	-	-	-	-	-	26.7%	53.3%	46.7%	33.3%	40.0%	40.0%	40.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
ADRENAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	60.0%	90.0%	90.0%	90.0%	80.0%
Dilation; vascular	10.0%	10.0%	40.0%	10.0%	10.0%	10.0%	10.0%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
ADRENAL GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	70.0%	100.0%	80.0%	100.0%	80.0%
Dilation; vascular	10.0%	10.0%	30.0%	0.0%	20.0%	0.0%	10.0%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
AORTA ABDOMINALIS;							
Examined	(10)	(9)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	60.0%	100.0%	80.0%
Inflammation; mixed; surrounding tissue	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	20.0%
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
BONE, STERNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; muscle	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
BRAIN, BRAIN STEM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-
EPIDIDYMIS, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	30.0%	20.0%	10.0%	70.0%	30.0%	40.0%	10.0%
Infiltration, Lymphocytic	70.0%	80.0%	90.0%	30.0%	70.0%	60.0%	90.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
EPIDIDYMIS, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	30.0%	10.0%	30.0%	40.0%	20.0%	40.0%	0.0%
Infiltration, Lymphocytic	70.0%	90.0%	70.0%	50.0%	80.0%	60.0%	100.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
ESOPHAGUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EYE, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	90.0%	90.0%	100.0%	90.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	10.0%	10.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	80.0%	100.0%	90.0%	100.0%	80.0%	70.0%	100.0%
Infiltration, Lymphocytic	20.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	90.0%	80.0%	90.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%
INJECTION SITE I;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	40.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Fibrosis; intramuscular / interstitial	0.0%	90.0% **	100.0% **	90.0% **	90.0% **	90.0% **	100.0% **
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	90.0% **	100.0% **	90.0% **	100.0% **
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Hemorrhage; subcutis	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	60.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; neutrophilic; dermis; epidermis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; plasmacytic; perivascular	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Inflammation; vascular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)							
Inflammation; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	90.0% **	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	90.0% **	100.0% **	100.0% **	90.0% **	90.0% **	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	90.0% **	100.0% **
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Necrosis; dermis; subcutis	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermis	0.0%	20.0%	20.0%	0.0%	0.0%	10.0%	0.0%
Degeneration; myofiber	10.0%	90.0% **	90.0% **	90.0% **	100.0% **	80.0% **	100.0% **
Regeneration; muscle	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Material; hair	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	60.0% *	100.0% **	90.0% **	80.0% **	90.0% **	100.0% **
Edema; intramuscular / interstitial	0.0%	20.0%	70.0% **	80.0% **	80.0% **	90.0% **	100.0% **
Edema; inter- / perimuscular	0.0%	70.0% **	100.0% **	100.0% **	80.0% **	90.0% **	100.0% **
Hyperkeratosis; epidermal	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	90.0% **	90.0% **	90.0% **	100.0% **	90.0% **	90.0% **
Scab; epidermal	0.0%	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%
Pustule; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;							
Examined	(10)	(4)	(0)	(0)	(10)	(0)	(10)
Within Normal Limits	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Degeneration; myofiber	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	100.0% **
Regeneration; muscle	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	70.0% **
Scab; epidermal	0.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; inter- / perimuscular	0.0%	50.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Necrosis; myofiber	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)							
Necrosis; dermis; subcutis	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; traumatic; myofiber	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Fibrosis; inter- / perimuscular	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	100.0% **
Fibrosis; intramuscular / interstitial	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	90.0% **
Ulceration; epidermal	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Inflammation; lymphohistiocytic	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	100.0% **
INTESTINE, CECUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	70.0%	100.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	10.0%	30.0%	0.0%	0.0%
INTESTINE, COLON;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	80.0%	80.0%	70.0%	70.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	10.0%	0.0%	20.0%	20.0%	10.0%	30.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	10.0%	30.0%	0.0%	0.0%
INTESTINE, DUODENUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INTESTINE, ILEUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	80.0%	80.0%	60.0%	100.0%	100.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	20.0%	30.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	10.0%	10.0%	20.0%	0.0%	10.0%	0.0%	0.0%
KIDNEY, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Congestion	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%
Basophilia; tubule	10.0%	10.0%	0.0%	20.0%	10.0%	20.0%	20.0%
Infiltration, Lymphocytic	20.0%	10.0%	30.0%	20.0%	0.0%	0.0%	20.0%
Mineralization	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	10.0%
Cyst; tubular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	10.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	20.0%
KIDNEY, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	0.0%	10.0%	10.0%	20.0%	20.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, RIGHT; (continued)							
Infiltration, Lymphocytic	0.0%	10.0%	30.0%	0.0%	10.0%	0.0%	0.0%
Inflammation; purulent; pelvis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Dilation; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration, Neutrophilic; subcapsular	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hematopoiesis; extramedullary	20.0%	40.0%	20.0%	30.0%	10.0%	10.0%	20.0%
Infiltration; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Necrosis	10.0%	0.0%	0.0%	10.0%	0.0%	10.0%	10.0%
Infiltration, Neutrophilic	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	50.0%	0.0%	50.0%	40.0%	20.0%	0.0%	30.0%
Vacuolation; hepatocellular	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Vacuolation; hepatocellular; periportal	0.0%	10.0%	10.0%	0.0%	80.0% **	10.0%	90.0% **
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Pigmentation; brown; kupffer cell	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LUNGS WITH BRONCHI;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	20.0%	30.0%	30.0%	20.0%	30.0%	40.0%	50.0%
Ossification	0.0%	10.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	40.0%	20.0%	50.0%	30.0%	20.0%	10.0%	30.0%
Hyperplasia; bronchial-associated lymphoid tissue	40.0%	60.0%	30.0%	60.0%	40.0%	30.0%	20.0%
Infiltration, Eosinophilic; perivascular	20.0%	0.0%	10.0%	20.0%	30.0%	10.0%	10.0%
Infiltration; foamy; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LYMPH NODE, CERVICAL;							
Examined	(8)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Histocytosis	100.0%	100.0%	90.0%	100.0%	100.0%	90.0%	80.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%	90.0%
LYMPH NODE, ILIAC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	90.0%	100.0%	90.0%	100.0%	100.0%	90.0%
Plasmacytosis	0.0%	50.0% *	70.0% **	90.0% **	80.0% **	60.0% *	100.0% **
Infiltration, Eosinophilic	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, ILIAC; (continued)							
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation	0.0%	50.0% *	0.0%	0.0%	50.0% *	40.0%	90.0% **
Increased Cellularity; germinal center	80.0%	90.0%	90.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, MESENTERIC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Increased Cellularity; germinal center	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, RENAL;							
Examined	(0)	(0)	(0)	(0)	(1)	(0)	(1)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Increased Cellularity; germinal center	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
MAMMARY GLANDS;							
Examined	(9)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	60.0%	100.0%
Inflammation; mixed; interstitium	0.0%	0.0%	0.0%	0.0%	20.0%	30.0%	0.0%
Inflammation; mixed; interstitium; lymphatic	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SKELETAL MUSCLE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	50.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	50.0% *
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	30.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NERVE, SCIATIC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	70.0%	100.0%	90.0%	30.0%	100.0%	0.0%
Inflammation; perineural	0.0%	30.0%	0.0%	10.0%	70.0% **	0.0%	100.0% **
Vacuolation	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, RIGHT;							
Examined	(10)	(7)	(10)	(9)	(10)	(10)	(9)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
OVARY, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVARY, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
PANCREAS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%
Atrophy; acinar cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; acinar cell	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
PARATHYROID, LEFT;							
Examined	(6)	(10)	(8)	(2)	(9)	(8)	(7)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PARATHYROID, LEFT; (continued)							
Fibrosis; interstitial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
PARATHYROID, RIGHT;							
Examined	(9)	(7)	(7)	(5)	(7)	(7)	(7)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(8)	(6)	(9)	(9)	(10)	(10)	(9)
Within Normal Limits	12.5%	16.7%	0.0%	0.0%	10.0%	0.0%	0.0%
Mineralization	0.0%	16.7%	22.2%	11.1%	0.0%	20.0%	11.1%
Inflammation, Granulomatous; follicular	0.0%	0.0%	11.1%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	87.5%	83.3%	100.0%	100.0%	90.0%	100.0%	100.0%
PITUITARY GLAND;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	70.0%
Cyst; pars distalis	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	30.0%
PROSTATE GLAND;							
Examined	(10)	(9)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	70.0%	88.9%	80.0%	80.0%	88.9%	90.0%	100.0%
Infiltration; mixed	0.0%	11.1%	10.0%	10.0%	0.0%	0.0%	0.0%
Inflammation; purulent	10.0%	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%
Infiltration, Lymphocytic	20.0%	0.0%	10.0%	0.0%	11.1%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(10)	(10)	(9)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SEMINAL VESICLES;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; fat	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
SKIN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	90.0%
Infiltration; mixed; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed; subcutaneous	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Necrosis; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Infiltration, Neutrophilic; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
SPINAL CORD;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SPINAL CORD; (continued)							
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SPLEEN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10.0%	0.0%	50.0%	10.0%	20.0%	50.0%	50.0%
Congestion	90.0%	100.0%	40.0%	90.0%	60.0%	50.0%	40.0%
Hematopoiesis; increased	0.0%	0.0%	30.0%	0.0%	20.0%	0.0%	20.0%
STOMACH, GLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10.0%	0.0%	50.0%	0.0%	0.0%	40.0%	0.0%
Infiltration, Eosinophilic	90.0%	90.0%	40.0%	100.0%	100.0%	50.0%	90.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Dilation; glandular	0.0%	20.0%	10.0%	10.0%	0.0%	10.0%	10.0%
Cyst	10.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; chief cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	10.0%	0.0%	0.0%	10.0%	10.0%
Infiltration, Neutrophilic; mucosa	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
STOMACH, NONGLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TESTIS, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
THYMUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	70.0%	30.0%	40.0%	50.0%	60.0%	50.0%	50.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	30.0%	70.0%	60.0%	50.0%	40.0%	50.0%	50.0%
THYROID, LEFT;							
Examined	(10)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	80.0%	100.0%	100.0%	100.0%	90.0%	100.0%
Cyst; keratinized	10.0%	20.0%	0.0%	0.0%	0.0%	10.0%	0.0%
TONGUE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TRACHEA; (continued)							
Within Normal Limits	50.0%	100.0%	70.0%	80.0%	80.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	30.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	10.0%	0.0%	20.0%	20.0%	20.0%	0.0%	0.0%
Pigmentation; brown; macrophage	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
URINARY BLADDER;							
Examined	(10)	(9)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	88.9%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	10.0%	11.1%	0.0%	0.0%	0.0%
UTERUS;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Dilation	-	-	-	-	-	-	-
VAGINA;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
ADRENAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	80.0%	70.0%	90.0%	90.0%	90.0%	80.0%
Dilation; vascular	0.0%	20.0%	20.0%	10.0%	10.0%	10.0%	20.0%
Hypertrophy; cortical	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	80.0%	100.0%	80.0%	100.0%	100.0%
Dilation; vascular	10.0%	10.0%	10.0%	0.0%	20.0%	0.0%	0.0%
Hypertrophy; cortical	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
AORTA ABDOMINALIS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	90.0%	100.0%	40.0%	100.0%	10.0%
Inflammation; mixed; surrounding tissue	0.0%	10.0%	10.0%	0.0%	60.0% *	0.0%	90.0% **
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
BONE, STERNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	100.0%	90.0%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; muscle	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%	0.0%
BRAIN, BRAIN STEM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	80.0%	60.0%	70.0%	90.0%	90.0%	70.0%	88.9%
Keratinization; epithelial	20.0%	40.0%	30.0%	10.0%	10.0%	30.0%	11.1%
EPIDIDYMIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
EPIDIDYMIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
Infiltration; mixed	-	-	-	-	-	-	-
ESOPHAGUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EYE, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	70.0%	60.0%	70.0%	90.0%	60.0%	100.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	10.0%	10.0%	10.0%	0.0%
Infiltration; lymphohistiocytic	10.0%	10.0%	10.0%	10.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	20.0%	10.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%	70.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	30.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	80.0%	90.0%	90.0%	100.0%	90.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	10.0%	10.0%	0.0%	0.0%	10.0%	0.0%
INJECTION SITE I;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; intramuscular / interstitial	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Hemorrhage	10.0%	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%
Hemorrhage; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	30.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; dermis; subcutis	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; neutrophilic; dermis; epidermis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Inflammation; plasmacytic; perivascular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; vascular	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)							
Inflammation; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Necrosis; myofiber	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%	0.0%
Necrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermis	0.0%	30.0%	0.0%	0.0%	0.0%	20.0%	20.0%
Degeneration; myofiber	0.0%	90.0% **	90.0% **	100.0% **	100.0% **	90.0% **	100.0% **
Regeneration; muscle	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Material; hair	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	100.0% **	90.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Edema; intramuscular / interstitial	0.0%	100.0% **	80.0% **	90.0% **	100.0% **	100.0% **	100.0% **
Edema; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Hyperkeratosis; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	90.0% **	70.0% **	80.0% **	100.0% **	100.0% **	100.0% **
Scab; epidermal	0.0%	20.0%	0.0%	0.0%	0.0%	10.0%	10.0%
Pustule; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
INJECTION SITE II;							
Examined	(10)	(0)	(0)	(0)	(10)	(0)	(10)
Within Normal Limits	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Degeneration; myofiber	10.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Regeneration; muscle	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	90.0% **
Scab; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)							
Necrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; traumatic; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Fibrosis; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Ulceration; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
INTESTINE, CECUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	80.0%	80.0%	100.0%	90.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	20.0%	20.0%	0.0%	10.0%
INTESTINE, COLON;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	80.0%	80.0%	80.0%	70.0%	90.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	20.0%	20.0%	10.0%	30.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	20.0%	10.0%	0.0%	10.0%
INTESTINE, DUODENUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INTESTINE, ILEUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	80.0%	90.0%	50.0%	80.0%	90.0%	40.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	50.0% *	20.0%	0.0%	50.0% *
Hyperplasia; mucosa-associated lymphoid tissue	10.0%	20.0%	10.0%	0.0%	10.0%	10.0%	10.0%
KIDNEY, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	10.0%	0.0%	0.0%	10.0%	10.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	0.0%
Mineralization	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%	10.0%
Cyst; tubular	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, RIGHT; (continued)							
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; purulent; pelvis	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Dilation; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; subcapsular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(10)	(10)	(9)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hematopoiesis; extramedullary	30.0%	30.0%	10.0%	70.0%	50.0%	60.0%	50.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	70.0%	10.0% *	30.0%	40.0%	0.0%	10.0% *	20.0%
Vacuolation; hepatocellular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; hepatocellular; periportal	0.0%	100.0% **	60.0% *	100.0% **	100.0% **	100.0% **	100.0% **
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; kupffer cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LUNGS WITH BRONCHI;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	80.0%	70.0%	50.0%	30.0%	30.0%	50.0%	20.0%
Ossification	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	20.0%	10.0%	10.0%	10.0%	0.0%
Hyperplasia; bronchial-associated lymphoid tissue	10.0%	20.0%	40.0%	40.0%	30.0%	50.0%	40.0%
Infiltration, Eosinophilic; perivascular	10.0%	0.0%	10.0%	40.0%	20.0%	0.0%	60.0%
Infiltration; foamy; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LYMPH NODE, CERVICAL;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	90.0%	90.0%	100.0%	100.0%	100.0%	80.0%	90.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	20.0%	10.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	80.0%	100.0%	100.0%	90.0%	100.0%	100.0%	80.0%
LYMPH NODE, ILIAC;							
Examined	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	90.0%	90.0%	60.0%	70.0%	100.0%	100.0%	90.0%
Plasmacytosis	0.0%	30.0%	70.0% **	80.0% **	100.0% **	70.0% **	100.0% **
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	11.1%	0.0%	0.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, ILIAC; (continued)							
Hemorrhage; acute	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation	0.0%	60.0% *	30.0%	0.0%	77.8% **	70.0% **	60.0% *
Increased Cellularity; germinal center	30.0%	80.0%	100.0% **	80.0%	100.0% **	100.0% **	100.0% **
LYMPH NODE, MESENTERIC;							
Examined	(9)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%
LYMPH NODE, RENAL;							
Examined	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
MAMMARY GLANDS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	70.0%	100.0%	90.0%	70.0%	100.0%
Inflammation; mixed; interstitium	0.0%	0.0%	30.0%	0.0%	10.0%	30.0%	0.0%
Inflammation; mixed; interstitium; lymphatic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SKELETAL MUSCLE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	100.0%	100.0%	70.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration; mixed	0.0%	10.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NERVE, SCIATIC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	80.0%	60.0%	0.0%	100.0%	0.0%
Inflammation; perineural	0.0%	0.0%	10.0%	40.0%	100.0% **	0.0%	100.0% **
Vacuolation	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, LEFT;							
Examined	(10)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	80.0%	90.0%	100.0%	100.0%	90.0%	90.0%
Hemorrhage; acute	0.0%	20.0%	0.0%	0.0%	0.0%	10.0%	10.0%
Pigmentation; brown; macrophage	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, RIGHT;							
Examined	(10)	(9)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	88.9%	90.0%	90.0%	100.0%	90.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	11.1%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
OVARY, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVARY, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, LEFT;							
Examined	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PANCREAS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	90.0%	90.0%	100.0%	100.0%	100.0%
Atrophy; acinar cell	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Hyperplasia; acinar cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
PARATHYROID, LEFT;							
Examined	(10)	(10)	(6)	(9)	(7)	(10)	(4)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	85.7%	100.0%	75.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PARATHYROID, LEFT; (continued)							
Fibrosis; interstitial	0.0%	10.0%	0.0%	0.0%	14.3%	0.0%	25.0%
PARATHYROID, RIGHT;							
Examined	(9)	(10)	(6)	(9)	(6)	(8)	(7)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(10)	(6)	(8)	(8)	(8)	(7)	(9)
Within Normal Limits	0.0%	0.0%	12.5%	0.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	14.3%	11.1%
Inflammation, Granulomatous; follicular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	87.5%	100.0%	100.0%	100.0%	100.0%
PITUITARY GLAND;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	100.0%	90.0%	100.0%
Cyst; pars distalis	0.0%	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%
PROSTATE GLAND;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration; mixed	-	-	-	-	-	-	-
Inflammation; purulent	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(9)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SEMINAL VESICLES;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration; mixed; surrounding tissue; fat	-	-	-	-	-	-	-
SKIN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	70.0%	100.0%	40.0%
Infiltration; mixed; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	30.0%	0.0%	60.0% *
Infiltration; mixed; subcutaneous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SPINAL CORD;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SPINAL CORD; (continued)							
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
SPLEEN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	10.0%	60.0%	10.0%	30.0%	30.0%	0.0%
Congestion	100.0%	90.0%	30.0% **	90.0%	40.0% *	70.0%	70.0%
Hematopoiesis; increased	0.0%	0.0%	20.0%	0.0%	70.0% **	0.0%	80.0% **
STOMACH, GLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	30.0%	50.0%	0.0%	0.0%	60.0%	10.0%
Infiltration, Eosinophilic	100.0%	50.0% *	40.0% *	100.0%	100.0%	30.0% **	80.0%
Infiltration, Lymphocytic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Dilation; glandular	0.0%	10.0%	20.0%	10.0%	0.0%	10.0%	10.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; chief cell	0.0%	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration, Neutrophilic; mucosa	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
STOMACH, NONGLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TESTIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
THYMUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	30.0%	20.0%	80.0%	60.0%	50.0%	50.0%	20.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Hemorrhage; acute	70.0%	80.0%	20.0%	40.0%	50.0%	40.0%	80.0%
THYROID, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	70.0%	90.0%	100.0%	90.0%	100.0%	100.0%
Cyst; keratinized	10.0%	30.0%	10.0%	0.0%	10.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	88.9%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	11.1%	0.0%
TONGUE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TRACHEA; (continued)							
Within Normal Limits	80.0%	90.0%	90.0%	70.0%	90.0%	90.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	20.0%	0.0%	10.0%	30.0%	10.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%
URINARY BLADDER;							
Examined	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	88.9%	100.0%	90.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	11.1%	0.0%	10.0%
UTERUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	70.0%	60.0%	80.0%	100.0%	100.0%	90.0%
Dilation	0.0%	30.0%	40.0%	20.0%	0.0%	0.0%	10.0%
VAGINA;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	70.0%	50.0%	50.0%	90.0%	80.0%	60.0%	70.0%
Keratinization; epithelial	30.0%	50.0%	50.0%	10.0%	20.0%	40.0%	30.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ADRENAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	40.0%	80.0%	40.0%	60.0%	80.0%	60.0%
Dilation; vascular	20.0%	60.0%	20.0%	60.0%	40.0%	20.0%	40.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	60.0%	100.0%	100.0%	80.0%	60.0%	60.0%
Dilation; vascular	20.0%	40.0%	0.0%	0.0%	20.0%	40.0%	40.0%
AORTA ABDOMINALIS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%
Infiltration, Lymphocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Infiltration; lymphohistiocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, STERNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
BRAIN, BRAIN STEM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-
Cyst; keratinized	-	-	-	-	-	-	-
EPIDIDYMIS, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	0.0%	20.0%	20.0%	40.0%	20.0%	60.0%
Infiltration, Lymphocytic	80.0%	100.0%	80.0%	80.0%	60.0%	80.0%	40.0%
EPIDIDYMIS, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	40.0%	20.0%	0.0%	20.0%	40.0%	0.0%	40.0%
Infiltration, Lymphocytic	60.0%	80.0%	100.0%	80.0%	60.0%	100.0%	60.0%
Oligospermia	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ESOPHAGUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HARDERIAN GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	60.0%	80.0%	80.0%	100.0%	100.0%	60.0%
Infiltration; lymphohistiocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
HEART; (continued)							
Infiltration, Lymphocytic	0.0%	20.0%	20.0%	20.0%	0.0%	0.0%	40.0%
INJECTION SITE I;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	80.0%	0.0%
Fibrosis; intramuscular / interstitial	0.0%	20.0%	60.0%	80.0% *	80.0% *	0.0%	80.0% *
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	20.0%	100.0% **
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	40.0%	40.0%	100.0% **	80.0% *	0.0%	60.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	100.0% **	80.0% *	100.0% **	100.0% **	20.0%	100.0% **
Mineralization; inter- / perimuscular	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Multinucleated Macrophages; inter- / perimuscular	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;							
Examined	(5)	(1)	(0)	(0)	(5)	(0)	(5)
Within Normal Limits	100.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Fibrosis; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	80.0% *	0.0%	80.0% *
Fibrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	80.0% *
INTESTINE, CECUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INTESTINE, COLON;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	20.0%	100.0%	60.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INTESTINE, COLON; (continued)							
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	20.0%	80.0% *	0.0%	40.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INTESTINE, DUODENUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, ILEUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	60.0%	60.0%	100.0%	60.0%	80.0%	60.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	20.0%	40.0%	40.0%	0.0%	40.0%	20.0%	40.0%
Nematodiasis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	20.0%	0.0%	20.0%	0.0%	0.0%	20.0%	0.0%
Infiltration, Lymphocytic	40.0%	0.0%	20.0%	20.0%	20.0%	0.0%	20.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
KIDNEY, LEFT; (continued)							
Degeneration; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	40.0%
Infiltration, Lymphocytic	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pyelonephritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Congestion	100.0%	100.0%	80.0%	100.0%	100.0%	80.0%	100.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%	0.0%
Infiltration, Lymphocytic	80.0%	100.0%	100.0%	80.0%	80.0%	40.0%	40.0%
Vacuolation; hepatocellular	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LIVER; (continued)							
Vacuolation; hepatocellular; periportal	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LUNGS WITH BRONCHI;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	20.0%	60.0%	20.0%	40.0%	20.0%	40.0%
Ossification	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	20.0%	0.0%	40.0%	20.0%	60.0%	40.0%
Hyperplasia; bronchial-associated lymphoid tissue	60.0%	60.0%	40.0%	60.0%	40.0%	60.0%	20.0%
Infiltration, Eosinophilic; perivascular	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; macrophage; alveolus	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LYMPH NODE, CERVICAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	60.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, ILIAC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%
Plasmacytosis	0.0%	0.0%	0.0%	40.0%	60.0%	0.0%	20.0%
Infiltration; macrophage	0.0%	0.0%	20.0%	20.0%	100.0% **	60.0%	100.0% **
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, MESENTERIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
MAMMARY GLANDS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SKELETAL MUSCLE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NERVE, SCIATIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	60.0%
Inflammation; perineural	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	40.0%
OPTIC NERVE, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
OPTIC NERVE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	80.0%	80.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
OVARY, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVARY, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
PANCREAS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PARATHYROID, LEFT;							
Examined	(2)	(2)	(3)	(5)	(5)	(4)	(4)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PARATHYROID, RIGHT;							
Examined	(4)	(3)	(4)	(3)	(4)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(4)	(3)	(4)	(5)	(5)	(4)	(3)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	0.0%
Mineralization	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Granulomatous; follicular	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	75.0%	100.0%
PITUITARY GLAND;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; pars distalis	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cyst; pars intermedia	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
PROSTATE GLAND;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	40.0%	20.0%	80.0%	40.0%	60.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%	0.0%
Infiltration, Lymphocytic	0.0%	20.0%	60.0%	80.0% *	0.0%	40.0%	40.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(5)	(5)	(5)	(5)	(4)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SEMINAL VESICLES;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SKIN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPINAL CORD;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPLEEN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	40.0%	20.0%	60.0%	60.0%	60.0%	60.0%	60.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SPLEEN; (continued)							
Congestion	60.0%	80.0%	40.0%	40.0%	40.0%	40.0%	40.0%
STOMACH, GLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	40.0%	20.0%	20.0%	0.0%
Infiltration, Eosinophilic	100.0%	100.0%	100.0%	60.0%	80.0%	80.0%	100.0%
Dilation; glandular	0.0%	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
STOMACH, NONGLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Spermatid Giant Cells	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dilation; tubular	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
TESTIS, RIGHT;							
Examined	(5)	(4)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Dilation; tubular	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration; lymphoplasmacytic	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spermatocoele	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
THYMUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	80.0%	60.0%	80.0%	60.0%	40.0%	60.0%
Hemorrhage; acute	40.0%	20.0%	40.0%	20.0%	40.0%	60.0%	40.0%
THYROID, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TONGUE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%
Granuloma	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Granuloma; hair	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%	0.0%
URINARY BLADDER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
URINARY BLADDER; (continued)							
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
UTERUS;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Dilation	-	-	-	-	-	-	-
VAGINA;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ADRENAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	40.0%	80.0%	40.0%	60.0%	100.0%	80.0%	80.0%
Dilation; vascular	60.0%	20.0%	60.0%	40.0%	0.0%	20.0%	20.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	100.0%	60.0%	100.0%	100.0%	80.0%
Dilation; vascular	20.0%	20.0%	0.0%	40.0%	0.0%	0.0%	20.0%
AORTA ABDOMINALIS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%
Infiltration, Lymphocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, STERNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
BRAIN, BRAIN STEM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	40.0%	60.0%	20.0%	40.0%	60.0%	60.0%
Keratinization; epithelial	20.0%	60.0%	40.0%	80.0%	60.0%	40.0%	40.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
EPIDIDYMIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
Oligospermia	-	-	-	-	-	-	-

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ESOPHAGUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	80.0%	100.0%	80.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
HARDERIAN GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	80.0%	100.0%	100.0%	80.0%	80.0%
Infiltration, Lymphocytic	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%	20.0%
Inflammation, Chronic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
HEART; (continued)							
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
INJECTION SITE I;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%
Fibrosis; intramuscular / interstitial	0.0%	60.0%	20.0%	80.0% *	20.0%	0.0%	80.0% *
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	80.0% *	80.0% *
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	80.0% *	20.0%	80.0% *	20.0%	0.0%	80.0% *
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	80.0% *	60.0%	100.0% **	80.0% *	60.0%	80.0% *
Mineralization; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Multinucleated Macrophages; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;							
Examined	(5)	(1)	(0)	(0)	(5)	(0)	(5)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
Fibrosis; inter- / perimuscular	0.0%	100.0%	0.0%	0.0%	80.0% *	0.0%	80.0% *
Fibrosis; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	40.0%
Fibrosis; dermis; subcutis	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	60.0%	0.0%	80.0% *
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	60.0%
INTESTINE, CECUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	80.0%	80.0%	100.0%	100.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	20.0%	20.0%	20.0%	0.0%	0.0%	0.0%
INTESTINE, COLON;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	80.0%	80.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INTESTINE, COLON; (continued)							
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
INTESTINE, DUODENUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, ILEUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	80.0%	100.0%	80.0%	100.0%	100.0%	60.0%
Infiltration, Eosinophilic; increased	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%	20.0%
Nematodiasis	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Basophilia; tubule	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Cast; hyaline; tubule	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%

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Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
KIDNEY, LEFT; (continued)							
Degeneration; hyaline; tubule	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%	0.0%
Cast; hyaline; tubule	20.0%	0.0%	20.0%	20.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Pyelonephritis	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	40.0%	60.0%	80.0%	40.0%	40.0%	80.0%	0.0%
Vacuolation; hepatocellular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LIVER; (continued)							
Vacuolation; hepatocellular; periportal	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
LUNGS WITH BRONCHI;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	20.0%	80.0%	40.0%	60.0%	100.0%	40.0%
Ossification	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	20.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; bronchial-associated lymphoid tissue	20.0%	40.0%	0.0%	60.0%	20.0%	0.0%	20.0%
Infiltration, Eosinophilic; perivascular	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	40.0%
Infiltration; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
LYMPH NODE, CERVICAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	80.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, ILIAC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	60.0%	100.0%	100.0%	100.0%
Plasmacytosis	0.0%	60.0%	60.0%	60.0%	100.0% **	20.0%	100.0% **
Infiltration; macrophage	0.0%	60.0%	0.0%	60.0%	100.0% **	100.0% **	100.0% **
Increased Cellularity; germinal center	80.0%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, MESENTERIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	60.0%
MAMMARY GLANDS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SKELETAL MUSCLE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	80.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
NERVE, SCIATIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(4)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	80.0%
Inflammation; perineural	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
OPTIC NERVE, LEFT;							
Examined	(4)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
OPTIC NERVE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
OVARY, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVARY, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(4)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PANCREAS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PARATHYROID, LEFT;							
Examined	(4)	(5)	(1)	(4)	(3)	(4)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PARATHYROID, RIGHT;							
Examined	(3)	(5)	(4)	(4)	(2)	(4)	(4)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(5)	(5)	(5)	(5)	(4)	(4)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	40.0%	0.0%	0.0%	20.0%
Mineralization	0.0%	0.0%	20.0%	0.0%	25.0%	0.0%	0.0%
Inflammation, Granulomatous; follicular	0.0%	0.0%	20.0%	20.0%	25.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	60.0%	100.0%	100.0%	80.0%
PITUITARY GLAND;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%
Cyst; pars distalis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cyst; pars intermedia	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
PROSTATE GLAND;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Inflammation; purulent	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SEMINAL VESICLES;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
SKIN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPINAL CORD;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPLEEN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	40.0%	20.0%	40.0%	60.0%	0.0%	40.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SPLEEN; (continued)							
Congestion	40.0%	60.0%	80.0%	60.0%	40.0%	100.0%	60.0%
STOMACH, GLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	0.0%	20.0%	0.0%	0.0%	20.0%	40.0%
Infiltration, Eosinophilic	80.0%	100.0%	80.0%	100.0%	100.0%	80.0%	60.0%
Dilation; glandular	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
Cyst	20.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
STOMACH, NONGLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Spermatid Giant Cells	-	-	-	-	-	-	-
Dilation; tubular	-	-	-	-	-	-	-
TESTIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Dilation; tubular	-	-	-	-	-	-	-
Infiltration; lymphoplasmacytic	-	-	-	-	-	-	-
Spermatocoele	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
THYMUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	60.0%	80.0%	60.0%	100.0%	60.0%	80.0%
Hemorrhage; acute	20.0%	40.0%	20.0%	40.0%	0.0%	40.0%	20.0%
THYROID, LEFT;							
Examined	(5)	(5)	(4)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	80.0%	100.0%
Cyst; keratinized	0.0%	20.0%	0.0%	0.0%	0.0%	20.0%	0.0%
TONGUE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%
Granuloma	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Granuloma; hair	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	80.0%	100.0%	100.0%	100.0%	80.0%
Infiltration; lymphohistiocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	20.0%
URINARY BLADDER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
URINARY BLADDER; (continued)							
Within Normal Limits	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
UTERUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	80.0%	100.0%	100.0%
Dilation	0.0%	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%
VAGINA;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	40.0%	60.0%	20.0%	20.0%	60.0%	40.0%
Keratinization; epithelial	20.0%	60.0%	40.0%	80.0%	80.0%	40.0%	60.0%

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
ADRENAL GLAND, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	9	6	9	9	9	8	10	8	7	9	9	9	8
Dilation; vascular	(1)	(1)	(4)	(1)	(1)	(1)	(1)	(0)	(2)	(2)	(1)	(1)	(1)	(2)
minimal	1	1	4	1	1	1	1	0	2	2	1	1	1	2
Hypertrophy; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Vacuolation; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
ADRENAL GLAND, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	9	7	10	8	10	8	9	9	8	10	8	10	10
Dilation; vascular	(1)	(1)	(3)	(0)	(2)	(0)	(1)	(1)	(1)	(1)	(0)	(2)	(0)	(0)
minimal	1	1	3	0	2	0	1	1	1	1	0	2	0	0
Hypertrophy; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Vacuolation; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
AORTA ABDOMINALIS;														
Examined	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	9	10	10	10	10	10	10	10	10	10	10	10	10
Not Examined: NOT PRESENT	0	1	0	0	0	0	0	0	0	0	0	0	0	0
BONE, OS FEMORIS WITH JOINT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	6	10	8	10	9	9	10	4	10	1
Inflammation; mixed; surrounding tissue	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(1)	(0)	(4)	(0)	(3)
minimal	0	0	0	0	1	0	0	0	1	1	0	2	0	0
mild	0	0	0	0	1	0	0	0	0	0	0	2	0	3
Inflammation; mixed; surrounding tissue; focal	(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(6)
mild	0	0	0	0	1	0	2	0	0	0	0	1	0	4
moderate	0	0	0	0	1	0	0	0	0	0	0	1	0	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
BONE MARROW, OS FEMORIS WITH JOINT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	0	0	0	0	0	0	10	0	0	0	0	0	0
Increased Cellularity	(0)	(10)	(10)	(10)	(10)	(10)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	10	10	10	10	10	10	0	10	10	10	10	10	10
BONE, STERNUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	9	9	10	10	10	9	10	9	10	10
Not Examined: NO SECTION	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; surrounding tissue; muscle; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	1	0	0
Infiltration; mixed; surrounding tissue; muscle; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
BRAIN, BRAIN STEM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BRAIN, CEREBELLUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BRAIN, CEREBRUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
CERVIX;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	-	-	-	-	-	-	-	8	6	7	9	9	7	8
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	0	0	1
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(2)	(4)	(3)	(1)	(1)	(3)	(1)
minimal	-	-	-	-	-	-	-	0	0	0	0	1	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
CERVIX; (continued)														
mild	-	-	-	-	-	-	-	2	4	3	1	0	3	1
EPIDIDYMIS, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	3	2	1	7	3	4	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	1	0	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(7)	(8)	(9)	(3)	(6)	(6)	(8)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	7	8	9	3	6	6	8	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	3	1	3	4	2	4	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	0	0	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(7)	(9)	(7)	(5)	(8)	(6)	(9)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	7	9	7	5	8	6	9	-	-	-	-	-	-	-
Infiltration; mixed; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	1	0	0	0	-	-	-	-	-	-	-
ESOPHAGUS;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
EYE, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	9	10	10	10	10	10	10
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
EYE, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	9	9	10	9	9	7	6	7	9	6	10
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(2)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	1	1	0	0	0	2	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	1	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(1)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	1	0	0	0	0
mild	0	0	0	0	0	0	0	1	0	0	1	0	0	0
Infiltration; lymphohistiocytic; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	1	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Inflammation; granulomatous; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Inflammation; purulent; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Inflammation, Chronic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
HARDERIAN GLAND, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	8	10	9	10	8	7	10	10	10	9	10	10	10	7
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	1	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	1	0	0	0	0	0	0	0	0	0
Necrosis; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, RIGHT; (continued)														
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)
minimal	0	0	0	0	0	2	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Inflammation, Chronic; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
HEART;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	9	9	8	9	10	10	10	8	9	9	10	9	10
Infiltration; lymphohistiocytic; focal	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	1	0	0	0	0	0
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	1	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	1	0	0	0	1	0	0	0	1	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	1	0	0	0	0
INJECTION SITE I;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	4	0	0	0	0	1	0	5	0	0	0	0	0	0
Fibrosis; intramuscular / interstitial	(0)	(9)	(10)	(9)	(9)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	1	0	0	1	0	0	0	0	0	0	1	0	0
mild	0	8	10	9	8	8	10	0	10	10	10	9	10	10
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Fibrosis; inter- / perimuscular	(0)	(10)	(10)	(9)	(10)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
mild	0	10	10	9	10	8	10	0	10	10	10	10	10	10
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
Hemorrhage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(1)	(0)	(1)	(0)
mild	0	0	0	0	0	0	1	1	0	0	0	0	1	0
moderate	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Hemorrhage; subcutis; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Inflammation; granulomatous; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; lymphocytic; inter- / perimuscular; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Inflammation; lymphohistiocytic; focal	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; lymphohistiocytic; multifocal	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	4	0	0	0	0	0	0	2	0	0	0	0	0	0
Inflammation; lymphohistiocytic; dermis; subcutis; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; neutrophilic; dermis; epidermis; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Inflammation; plasmacytic; perivascular; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Inflammation; vascular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
moderate	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Inflammation; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; mixed; subcutis	(0)	(9)	(10)	(10)	(10)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
mild	0	0	0	1	2	0	0	0	0	0	0	0	0	0
moderate	0	9	10	7	8	9	9	0	10	10	10	10	10	10
marked	0	0	0	2	0	0	1	0	0	0	0	0	0	0
Inflammation; mixed; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
Inflammation; mixed; intramuscular / interstitial	(0)	(9)	(10)	(10)	(5)	(4)	(5)	(0)	(10)	(10)	(9)	(8)	(3)	(9)
minimal	0	1	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	4	8	1	3	4	4	0	8	4	4	8	3	9
moderate	0	4	2	9	1	0	1	0	2	6	5	0	0	0
Inflammation; mixed; intramuscular / interstitial; multifocal	(0)	(0)	(0)	(0)	(4)	(5)	(5)	(0)	(0)	(0)	(1)	(2)	(7)	(1)
moderate	0	0	0	0	4	5	5	0	0	0	1	2	7	1
Inflammation; mixed; inter- / perimuscular	(0)	(10)	(10)	(10)	(9)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	3	0	1	0	0	0	0	0	0	0	0	0	0
moderate	0	7	10	6	8	9	9	0	10	7	9	10	8	10
marked	0	0	0	3	0	0	1	0	0	3	1	0	2	0
Inflammation; mixed; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Necrosis; myofiber; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Necrosis; myofiber; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Necrosis; dermis; subcutis; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Ulceration; epidermis; focal	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(1)	(2)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
moderate	0	1	1	0	0	0	0	0	3	0	0	0	1	0
Ulceration; epidermis; multifocal	(0)	(1)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	1	0	0	0	1	0	0	0	0	0	0	0	0
moderate	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Degeneration; myofiber	(0)	(9)	(9)	(9)	(10)	(8)	(10)	(0)	(9)	(9)	(10)	(10)	(9)	(10)
minimal	0	2	0	1	1	0	0	0	0	0	2	2	0	0
mild	0	7	9	8	9	7	10	0	9	9	8	8	4	10

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
moderate	0	0	0	0	0	1	0	0	0	0	0	0	5	0
Degeneration; myofiber; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Regeneration; muscle; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Foreign Material; hair; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Edema; subcutis	(0)	(6)	(10)	(9)	(8)	(9)	(10)	(0)	(10)	(9)	(10)	(10)	(10)	(10)
mild	0	1	1	4	1	0	1	0	0	1	4	2	0	2
moderate	0	5	9	4	7	6	7	0	10	6	6	8	5	7
marked	0	0	0	1	0	3	2	0	0	2	0	0	5	1
Edema; intramuscular / interstitial	(0)	(2)	(7)	(8)	(8)	(9)	(10)	(0)	(10)	(8)	(9)	(10)	(10)	(10)
minimal	0	1	6	2	1	1	0	0	8	1	2	1	1	0
mild	0	1	1	6	7	8	10	0	2	7	7	9	9	10
Edema; inter- / perimuscular	(0)	(7)	(10)	(10)	(8)	(10)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(11)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
mild	0	2	5	3	0	2	0	0	1	0	1	2	1	0
moderate	0	4	5	6	8	6	6	0	9	8	8	6	8	6
marked	0	1	0	1	0	2	4	0	0	1	1	2	1	5
Hyperkeratosis; epidermal; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia; epidermal	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	2	0	0	0	0	0	0	0	0	0	0	0	0
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia; epidermal; widespread	(0)	(4)	(9)	(9)	(10)	(9)	(9)	(0)	(9)	(7)	(8)	(10)	(10)	(10)
mild	0	0	2	5	3	0	2	0	0	3	7	1	0	1
moderate	0	4	7	4	7	9	7	0	9	4	1	9	10	9
Hyperplasia; epidermal; focal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Scab; epidermal; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(1)
minimal	0	0	1	0	0	0	0	0	1	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Scab; epidermal; multifocal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	1	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
Pustule; epidermal; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
INJECTION SITE II;														
Examined	(10)	(4)	(0)	(0)	(10)	(0)	(10)	(10)	(0)	(0)	(0)	(10)	(0)	(10)
Within Normal Limits	5	0	0	0	0	0	0	5	0	0	0	0	0	0
Degeneration; myofiber	(0)	(3)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
minimal	0	0	0	0	0	0	0	0	0	0	0	2	0	2
mild	0	3	0	0	10	0	10	0	0	0	0	8	0	8
Degeneration; myofiber; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Regeneration; muscle	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Regeneration; muscle; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Hyperplasia; epidermal; widespread	(0)	(2)	(0)	(0)	(10)	(0)	(7)	(0)	(0)	(0)	(0)	(10)	(0)	(9)
mild	0	0	0	0	1	0	1	0	0	0	0	2	0	3
moderate	0	2	0	0	9	0	6	0	0	0	0	8	0	6
Hyperplasia; epidermal; focal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Scab; epidermal; focal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Edema; subcutis	(0)	(2)	(0)	(0)	(10)	(0)	(11)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	2
mild	0	0	0	0	3	0	1	0	0	0	0	1	0	1
moderate	0	2	0	0	4	0	6	0	0	0	0	9	0	4
marked	0	0	0	0	3	0	3	0	0	0	0	0	0	3
Edema; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Edema; inter- / perimuscular	(0)	(2)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	1	0	0	0	0	1	0	0	0	0	0	0	2
moderate	0	1	0	0	7	0	4	0	0	0	0	9	0	4
marked	0	0	0	0	3	0	5	0	0	0	0	1	0	4
Edema; intramuscular / interstitial	(0)	(0)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)														
minimal	0	0	0	0	0	0	1	0	0	0	0	1	0	2
mild	0	0	0	0	10	0	9	0	0	0	0	8	0	8
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Necrosis; myofiber; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis; myofiber; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Necrosis; dermis; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis; traumatic; myofiber; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis; subcutis	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Fibrosis; inter- / perimuscular	(0)	(2)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	2	0	0	10	0	10	0	0	0	0	10	0	10
Fibrosis; inter- / perimuscular; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis; intramuscular / interstitial	(0)	(2)	(0)	(0)	(10)	(0)	(9)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	2	0	0	10	0	9	0	0	0	0	10	0	10
Fibrosis; intramuscular / interstitial; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Ulceration; epidermal; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Inflammation; lymphohistiocytic; focal	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	0	0	0	0	0	2	0	0	0	0	0	0
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; lymphohistiocytic; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	2	0	0	0	0	0	0
Inflammation; mixed; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)														
Inflammation; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; mixed; subcutis	(0)	(3)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	0	0	0	1	0	0	0	0	0	0	1	0	2
moderate	0	3	0	0	9	0	10	0	0	0	0	9	0	8
Inflammation; mixed; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; inter- / perimuscular	(0)	(3)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
moderate	0	2	0	0	10	0	10	0	0	0	0	10	0	10
Inflammation; mixed; inter- / perimuscular; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; intramuscular / interstitial	(0)	(3)	(0)	(0)	(5)	(0)	(4)	(0)	(0)	(0)	(0)	(6)	(0)	(9)
mild	0	2	0	0	5	0	4	0	0	0	0	6	0	9
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; intramuscular / interstitial; multifocal	(0)	(1)	(0)	(0)	(5)	(0)	(6)	(0)	(0)	(0)	(0)	(4)	(0)	(1)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
moderate	0	0	0	0	5	0	6	0	0	0	0	4	0	1
INTESTINE, CECUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	8	7	10	10	10	10	9	8	8	10	9
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	2	0	0	0	0	0	1	0	0	0	0
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(1)	(3)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(1)
minimal	0	0	0	1	3	0	0	0	0	0	2	2	0	1
INTESTINE, COLON;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INTESTINE, COLON; (continued)														
Within Normal Limits	9	10	8	8	7	7	10	10	10	8	8	8	7	9
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(0)	(2)	(2)	(1)	(3)	(0)	(0)	(0)	(2)	(2)	(1)	(3)	(0)
minimal	0	0	1	0	0	1	0	0	0	0	0	0	1	0
mild	0	0	1	2	1	2	0	0	0	2	2	1	1	0
moderate	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(1)	(3)	(0)	(0)	(0)	(0)	(0)	(2)	(1)	(0)	(1)
minimal	0	0	0	1	3	0	0	0	0	0	2	1	0	1
INTESTINE, DUODENUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
INTESTINE, ILEUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
INTESTINE, JEJUNUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
INTESTINE, RECTUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	9	8	8	6	10	10	9	8	9	5	8	9	4
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(2)	(3)	(0)	(0)	(0)	(0)	(0)	(5)	(2)	(0)	(5)
minimal	0	0	0	1	3	0	0	0	0	0	5	2	0	5
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(1)	(2)	(0)	(1)	(0)	(0)	(1)	(2)	(1)	(0)	(1)	(1)	(1)
minimal	0	0	1	0	0	0	0	1	0	1	0	0	1	1
mild	1	1	1	0	1	0	0	0	2	0	0	1	0	0
KIDNEY, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, LEFT; (continued)														
Within Normal Limits	1	0	0	0	0	0	1	0	0	0	0	0	0	0
Congestion	(9)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
mild	2	4	5	4	3	1	1	3	5	5	3	5	8	5
moderate	7	6	5	6	7	9	8	7	5	5	7	5	2	5
Basophilia; tubule; focal	(1)	(1)	(0)	(1)	(1)	(2)	(1)	(1)	(0)	(0)	(1)	(1)	(0)	(0)
minimal	0	1	0	1	1	1	1	1	0	0	1	1	0	0
mild	1	0	0	0	0	1	0	0	0	0	0	0	0	0
Basophilia; tubule; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	1	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(0)	(1)	(1)	(1)	(0)
minimal	1	0	0	0	0	0	1	1	1	0	1	0	1	0
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(1)	(1)	(3)	(2)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	1	1	3	2	0	0	1	0	0	1	0	0	0	0
Mineralization; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Mineralization; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Cyst; tubular; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Inflammation, Chronic; interstitial; focal	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(1)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	1	1	0	0	0	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cast; hyaline; tubule; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	1	0	1	0	0	0	0	0
KIDNEY, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, RIGHT; (continued)														
mild	3	4	6	4	4	1	2	3	6	6	3	6	8	6
moderate	7	6	4	6	6	9	8	7	4	4	7	4	2	4
Basophilia; tubule; focal	(0)	(0)	(0)	(1)	(1)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	1	1	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	1	2	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(2)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	2	0	1	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; purulent; pelvis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Mineralization; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Mineralization; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Dilation; tubule; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration, Neutrophilic; subcapsular; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
LACRIMAL GLAND, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
LACRIMAL GLAND, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	9	10	10	10	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	1	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LIVER;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
mild	3	5	3	4	3	4	2	4	7	8	6	4	8	9
moderate	7	4	7	6	7	6	8	5	3	2	4	6	2	1
Hematopoiesis; extramedullary; focal	(0)	(0)	(0)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	2	0	1	0	0	0	0	0	0	0	0
Hematopoiesis; extramedullary; multifocal	(2)	(4)	(2)	(1)	(1)	(0)	(2)	(3)	(3)	(1)	(7)	(5)	(6)	(5)
minimal	2	4	2	1	1	0	2	3	3	1	7	5	6	5
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	1	0	0	0
Infiltration; mixed; multifocal	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis; focal	(1)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	1	0	0	1	0	0	0	0	0	0	0	0	0	0
Necrosis; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Infiltration, Neutrophilic; focal	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	1	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(5)	(0)	(5)	(3)	(2)	(0)	(2)	(7)	(1)	(3)	(4)	(0)	(1)	(2)
minimal	5	0	5	3	2	0	2	7	1	3	4	0	1	2
Vacuolation; hepatocellular; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Vacuolation; hepatocellular; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Vacuolation; hepatocellular; periportal	(0)	(1)	(1)	(0)	(8)	(1)	(9)	(0)	(10)	(6)	(10)	(10)	(10)	(10)
minimal	0	1	1	0	5	1	5	0	4	5	2	1	6	2
mild	0	0	0	0	3	0	4	0	6	1	8	9	4	8
Infiltration, Eosinophilic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LIVER; (continued)														
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Pigmentation; brown; kupffer cell	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
LUNGS WITH BRONCHI;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	2	3	3	2	3	4	5	8	7	5	3	3	5	2
Ossification; focal	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)
minimal	0	1	0	1	0	0	0	0	1	0	0	1	0	0
Hemorrhage; acute; focal	(1)	(0)	(4)	(0)	(2)	(1)	(2)	(0)	(0)	(2)	(1)	(1)	(1)	(0)
minimal	1	0	1	0	2	0	0	0	0	1	1	0	0	0
mild	0	0	3	0	0	1	2	0	0	1	0	1	1	0
Hemorrhage; acute; multifocal	(3)	(2)	(1)	(3)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	1	1	3	0	0	0	0	0	0	0	0	0	0
mild	2	1	0	0	0	0	1	0	0	0	0	0	0	0
Hyperplasia; bronchial-associated lymphoid tissue	(4)	(6)	(3)	(6)	(4)	(3)	(2)	(1)	(2)	(4)	(4)	(3)	(5)	(4)
minimal	4	6	3	6	4	3	2	1	2	3	4	3	5	4
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Infiltration, Eosinophilic; perivascular ; focal	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	1	0	0	0	0	0	0	0	0
Infiltration, Eosinophilic; perivascular ; multifocal	(2)	(0)	(0)	(2)	(3)	(0)	(1)	(1)	(0)	(1)	(4)	(2)	(0)	(6)
minimal	2	0	0	1	3	0	1	1	0	1	2	1	0	6
mild	0	0	0	1	0	0	0	0	0	0	2	1	0	0
Infiltration; foamy; macrophage; alveolus ; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Pigmentation; brown; macrophage; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LUNGS WITH BRONCHI; (continued)														
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
LYMPH NODE, CERVICAL;														
Examined	(8)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Histocytosis	(8)	(10)	(9)	(10)	(10)	(9)	(8)	(9)	(9)	(10)	(10)	(10)	(8)	(9)
minimal	8	7	7	8	5	6	4	8	6	6	10	4	3	3
mild	0	3	2	2	5	3	4	1	3	4	0	6	5	6
Erythrophagocytosis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Pigmentation; brown; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	2	1	0
Hemorrhage	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Plasmacytosis	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Increased Cellularity; germinal center	(8)	(10)	(10)	(9)	(10)	(10)	(9)	(8)	(10)	(10)	(9)	(10)	(10)	(8)
minimal	5	3	3	8	2	2	1	3	1	0	7	2	1	0
mild	3	7	7	1	8	8	5	4	9	10	2	8	8	8
moderate	0	0	0	0	0	0	3	1	0	0	0	0	1	0
LYMPH NODE, ILIAC;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Histocytosis	(10)	(9)	(10)	(9)	(10)	(10)	(9)	(9)	(9)	(6)	(7)	(9)	(10)	(9)
minimal	3	5	6	3	3	3	2	1	7	2	5	0	2	4
mild	7	4	4	6	7	7	7	8	2	4	2	9	8	5
Plasmacytosis	(0)	(5)	(7)	(9)	(8)	(6)	(10)	(0)	(3)	(7)	(8)	(9)	(7)	(10)
minimal	0	2	1	0	1	4	0	0	2	1	0	0	1	0
mild	0	3	6	2	4	1	9	0	1	6	1	4	6	2
moderate	0	0	0	7	2	1	1	0	0	0	7	5	0	8
marked	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, ILIAC; (continued)														
Infiltration, Eosinophilic	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	1	0	0	0	1	0	0	0	0	0	0	1	0	0
Hemorrhage; acute	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation	(0)	(5)	(0)	(0)	(5)	(4)	(9)	(0)	(6)	(3)	(0)	(7)	(7)	(6)
minimal	0	4	0	0	0	1	1	0	1	1	0	2	2	1
mild	0	1	0	0	3	1	7	0	5	2	0	3	3	5
moderate	0	0	0	0	2	2	1	0	0	0	0	2	2	0
Increased Cellularity; germinal center ..	(8)	(9)	(9)	(10)	(10)	(10)	(10)	(3)	(8)	(10)	(8)	(9)	(10)	(10)
minimal	4	3	0	1	1	0	0	3	1	1	2	0	0	0
mild	4	5	6	9	7	8	8	0	6	7	4	6	10	6
moderate	0	1	3	0	2	2	2	0	1	2	2	3	0	4
LYMPH NODE, MESENTERIC;														
Examined.....	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits.....	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Erythrophagocytosis	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Histocytosis	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	5	0	1	0	1	0	0	0	2	0	0	1	0	0
mild	5	10	9	8	9	9	9	9	6	10	10	9	9	9
moderate	0	0	0	2	0	1	1	0	2	0	0	0	1	1
Infiltration, Eosinophilic	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	1	0	0
Increased Cellularity; germinal center ..	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(9)	(10)
minimal	1	0	0	1	0	1	1	0	1	0	1	0	0	0
mild	8	10	10	9	10	9	9	9	9	10	9	10	9	10
LYMPH NODE, RENAL;														
Examined.....	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Within Normal Limits.....	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Histocytosis	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, RENAL; (continued)														
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Plasmacytosis	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Increased Cellularity; germinal center	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
MAMMARY GLANDS;														
Examined	(9)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	9	8	6	10	10	10	7	10	9	7	10
Not Examined: NOT PRESENT	1	0	0	1	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; interstitium	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation; mixed; interstitium; focal	(0)	(0)	(0)	(0)	(2)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(3)	(0)
mild	0	0	0	0	1	2	0	0	0	2	0	0	1	0
moderate	0	0	0	0	1	1	0	0	0	0	0	0	2	0
Inflammation; mixed; interstitium; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Inflammation; mixed; interstitium; lymphatic; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0
SKELETAL MUSCLE;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	9	10	5	9	9	10	10	7	10	10
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(2)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	1	0	0	2	0	0
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	4	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SKELETAL MUSCLE; (continued)														
Necrosis; myofiber; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	1	0	0
Necrosis; myofiber; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	2	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
NERVE, SCIATIC;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	7	10	9	3	10	0	10	10	8	6	0	10	0
Inflammation; perineural	(0)	(3)	(0)	(1)	(7)	(0)	(10)	(0)	(0)	(1)	(4)	(10)	(0)	(10)
minimal	0	0	0	0	3	0	1	0	0	1	1	1	0	1
mild	0	0	0	0	2	0	2	0	0	0	3	2	0	3
moderate	0	2	0	1	2	0	5	0	0	0	0	7	0	5
marked	0	1	0	0	0	0	2	0	0	0	0	0	0	1
Vacuolation; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OPTIC NERVE, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	8	9	9	10	9	9
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Hemorrhage; acute; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(1)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	1	1
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OPTIC NERVE, RIGHT;														
Examined	(10)	(7)	(10)	(9)	(10)	(10)	(9)	(10)	(9)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	7	10	9	10	10	9	10	8	9	9	10	9	10
Not Examined: NOT PRESENT	0	3	0	1	0	0	1	0	1	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
OPTIC NERVE, RIGHT; (continued)														
Hemorrhage; acute; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Infiltration; foamy; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OVARY, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	10	9	10
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	0	1	0
OVARY, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	10	10	10
OVIDUCT, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	9	10	10
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	1	0	0
OVIDUCT, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	10	10	10
PANCREAS;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	10	9	10	9	9	10	9	9	10	10	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Atrophy; acinar cell; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	1	0	0	0
Hyperplasia; acinar cell; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	1	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PARATHYROID, LEFT;														
Examined	(6)	(10)	(8)	(2)	(9)	(8)	(7)	(10)	(10)	(6)	(9)	(7)	(10)	(4)
Within Normal Limits	6	10	8	2	9	8	7	10	9	6	9	6	10	3
Not Examined: NOT PRESENT	4	0	2	8	1	2	3	0	0	4	1	3	0	6
Fibrosis; interstitial	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(1)
mild	0	0	0	0	0	0	0	0	1	0	0	1	0	1
PARATHYROID, RIGHT;														
Examined	(9)	(7)	(7)	(5)	(7)	(7)	(7)	(9)	(10)	(6)	(9)	(6)	(8)	(7)
Within Normal Limits	9	7	7	5	7	7	7	9	10	6	9	6	8	7
Not Examined: NOT PRESENT	1	3	3	5	3	3	3	1	0	4	1	4	2	3
PEYERS PATCHES;														
Examined	(8)	(6)	(9)	(9)	(10)	(10)	(9)	(10)	(6)	(8)	(8)	(8)	(7)	(9)
Within Normal Limits	1	1	0	0	1	0	0	0	0	1	0	0	0	0
Not Examined: NOT PRESENT	2	4	1	1	0	0	1	0	4	2	2	2	3	1
Mineralization; focal	(0)	(0)	(1)	(0)	(0)	(2)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(1)
minimal	0	0	1	0	0	2	1	0	0	0	0	0	1	1
Mineralization; multifocal	(0)	(1)	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
mild	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Inflammation, Granulomatous; follicular; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Increased Cellularity; germinal center	(7)	(5)	(9)	(9)	(9)	(10)	(9)	(10)	(6)	(7)	(8)	(8)	(7)	(9)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
mild	0	3	2	1	1	4	2	3	3	0	2	1	2	6
moderate	7	2	7	8	8	6	7	7	3	7	6	7	4	3
PITUITARY GLAND;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	10	9	10	10	10	10	7	10	9	10	10	10	9	9
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Cyst; pars distalis; few	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	2	0	0	0	0	0	1	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PITUITARY GLAND; (continued)														
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cyst; pars distalis; single	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	1	0	0	0	0	0
PROSTATE GLAND;														
Examined	(10)	(9)	(10)	(10)	(9)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	7	8	8	8	8	9	10	-	-	-	-	-	-	-
Not Examined: NO SECTION	0	1	0	0	1	0	0	-	-	-	-	-	-	-
Infiltration; mixed	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	1	0	0	0	0	0	-	-	-	-	-	-	-
Infiltration; mixed; focal	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	0	1	1	0	0	0	-	-	-	-	-	-	-
Inflammation; purulent; focal	(1)	(0)	(0)	(1)	(0)	(1)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	1	0	0	1	0	1	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	1	0	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	2	0	1	0	0	0	0	-	-	-	-	-	-	-
SALIVARY GLANDS, MANDIBULAR;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
SALIVARY GLANDS, SUBLINGUAL;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	9	10	10	9	10	10	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	1	0	0	1	0	0	0
SALIVARY GLANDS, PAROTIS;														
Examined	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	10	9	9	10	10	10	10	10	10	10	10	10	9	10
Not Examined: NOT PRESENT	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SEMINAL VESICLES;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	10	10	10	10	9	10	10	-	-	-	-	-	-	-
Infiltration; mixed; surrounding tissue; fat; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
moderate	0	0	0	0	1	0	0	-	-	-	-	-	-	-
SKIN;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	9	10	9	10	10	10	10	7	10	4
Infiltration; mixed; dermis; subcutis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(2)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	1
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; mixed; dermis; subcutis; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(4)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	1
moderate	0	0	0	0	0	0	0	0	0	0	0	0	0	2
Infiltration; mixed; subcutaneous; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Necrosis; muscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Infiltration, Neutrophilic; muscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
SPINAL CORD;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	9
Cyst; keratinized; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
SPLEEN;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SPLEEN; (continued)														
Within Normal Limits	1	0	5	1	2	5	5	0	1	6	1	3	3	0
Congestion	(9)	(10)	(4)	(9)	(6)	(5)	(4)	(10)	(9)	(3)	(9)	(4)	(7)	(7)
minimal	9	9	4	9	6	4	4	7	6	2	8	4	6	7
mild	0	1	0	0	0	1	0	3	3	1	1	0	1	0
Hematopoiesis; increased	(0)	(0)	(3)	(0)	(2)	(0)	(2)	(0)	(0)	(2)	(0)	(7)	(0)	(8)
minimal	0	0	3	0	0	0	2	0	0	2	0	4	0	6
mild	0	0	0	0	2	0	0	0	0	0	0	3	0	2
STOMACH, GLANDULAR;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	1	0	5	0	0	4	0	0	3	5	0	0	6	1
Infiltration, Eosinophilic	(9)	(9)	(4)	(10)	(10)	(5)	(9)	(10)	(5)	(4)	(10)	(10)	(3)	(8)
minimal	4	9	4	2	7	5	9	7	5	4	4	6	3	6
mild	4	0	0	8	3	0	0	3	0	0	6	4	0	2
moderate	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Dilation; glandular; focal	(0)	(0)	(1)	(0)	(0)	(1)	(1)	(0)	(0)	(1)	(1)	(0)	(1)	(0)
minimal	0	0	1	0	0	1	0	0	0	1	1	0	1	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Dilation; glandular; multifocal	(0)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(1)
minimal	0	2	0	1	0	0	0	0	1	1	0	0	0	1
Cyst; single	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia; chief cell	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Hyperplasia; chief cell; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(0)	(1)	(0)	(0)	(1)	(1)	(0)	(1)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	1	0	0	1	0	0	1	0	0	1	0	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
STOMACH, GLANDULAR; (continued)														
Infiltration, Neutrophilic; mucosa; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
STOMACH, NONGLANDULAR;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
TESTIS, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	10	10	10	10	10	10	10	-	-	-	-	-	-	-
TESTIS, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	10	10	10	10	10	10	10	-	-	-	-	-	-	-
THYMUS;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	7	3	4	5	6	5	5	3	2	8	6	5	5	2
Cyst; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Hemorrhage; acute; focal	(2)	(2)	(2)	(2)	(0)	(1)	(1)	(1)	(3)	(0)	(0)	(3)	(1)	(2)
minimal	2	1	2	1	0	1	0	1	2	0	0	3	1	2
mild	0	1	0	1	0	0	1	0	1	0	0	0	0	0
Hemorrhage; acute; multifocal	(1)	(5)	(4)	(3)	(4)	(4)	(4)	(6)	(5)	(2)	(4)	(2)	(3)	(6)
minimal	1	4	4	3	2	3	3	5	3	2	3	2	2	6
mild	0	1	0	0	2	1	1	1	2	0	1	0	1	0
THYROID, LEFT;														
Examined	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	9	10	10	10	9	7	9	10	9	10	10
Not Examined: NOT PRESENT	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Cyst; keratinized; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(3)	(1)	(0)	(1)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
THYROID, LEFT; (continued)														
minimal	1	0	0	0	0	0	0	1	3	1	0	1	0	0
THYROID, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	9	8	10	10	10	9	10	10	10	10	10	10	8	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Cyst; keratinized; multiple	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Cyst; keratinized; single	(1)	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	1	1	0	0	0	1	0	0	0	0	0	0	1	0
TONGUE;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	10	10	10	10	9	10	10	9	10	10	10
Hemorrhage; acute; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	1	0	0	0	0	0	0
TRACHEA;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	5	10	7	8	8	10	10	8	9	9	7	9	9	10
Infiltration; lymphohistiocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration; lymphohistiocytic; multifocal	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration; mixed	(1)	(0)	(2)	(2)	(2)	(0)	(0)	(2)	(0)	(1)	(3)	(1)	(0)	(0)
minimal	1	0	2	2	2	0	0	2	0	1	3	1	0	0
Pigmentation; brown; macrophage; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Infiltration, Lymphocytic; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TRACHEA; (continued)														
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
URINARY BLADDER;														
Examined	(10)	(9)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	10	9	9	8	10	10	10	9	10	10	10	8	10	9
Not Examined: INSUFFICIENT TISSUE TO EVALUATE	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Not Examined: NOT PRESENT	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)	(1)
minimal	0	0	1	1	0	0	0	1	0	0	0	1	0	1
UTERUS;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	7	6	8	10	10	9
Dilation	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(3)	(4)	(2)	(0)	(0)	(1)
mild	-	-	-	-	-	-	-	0	3	4	2	0	0	1
VAGINA;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	7	5	5	9	8	6	7
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(3)	(5)	(5)	(1)	(2)	(4)	(3)
minimal	-	-	-	-	-	-	-	1	1	2	0	2	1	1
mild	-	-	-	-	-	-	-	2	4	3	1	0	3	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ADRENAL GLAND, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	2	4	2	3	4	3	2	4	2	3	5	4	4
Dilation; vascular	(1)	(3)	(1)	(3)	(2)	(1)	(2)	(3)	(1)	(3)	(2)	(0)	(1)	(1)
minimal	1	3	1	3	2	1	2	3	1	3	2	0	1	1
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
ADRENAL GLAND, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	3	5	5	4	3	3	4	4	5	3	5	5	4
Dilation; vascular	(1)	(2)	(0)	(0)	(1)	(2)	(2)	(1)	(1)	(0)	(2)	(0)	(0)	(1)
minimal	1	2	0	0	1	2	2	1	1	0	2	0	0	1
AORTA ABDOMINALIS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BONE, OS FEMORIS WITH JOINT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	4	5	5	5	5	5	5	4	5	5
Infiltration, Lymphocytic; surrounding tissue; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Infiltration; lymphohistiocytic; surrounding tissue; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
BONE MARROW, OS FEMORIS WITH JOINT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BONE, STERNUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
BRAIN, BRAIN STEM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BRAIN, CEREBELLUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BRAIN, CEREBRUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CERVIX;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	4	2	3	1	2	3	3
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(1)	(3)	(2)	(4)	(3)	(2)	(2)
minimal	-	-	-	-	-	-	-	0	1	1	1	0	0	1
mild	-	-	-	-	-	-	-	1	2	1	3	3	2	1
Cyst; keratinized	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
moderate	-	-	-	-	-	-	-	0	0	0	0	0	1	0
EPIDIDYMIS, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	1	0	1	1	2	1	3	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	1	0	1	0	0	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(4)	(4)	(4)	(3)	(3)	(4)	(2)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	4	4	3	3	3	4	2	-	-	-	-	-	-	-
mild	0	0	1	0	0	0	0	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	2	1	0	1	2	0	2	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(3)	(4)	(5)	(4)	(3)	(5)	(3)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	3	4	5	4	3	5	3	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
EPIDIDYMIS, RIGHT; (continued)														
Oligospermia	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	0	0	1	0	0	0	-	-	-	-	-	-	-
ESOPHAGUS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
EYE, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
EYE, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
HARDERIAN GLAND, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	4	5	5	5	5	5	5	4	4	5	4
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Infiltration, Lymphocytic; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation, Chronic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
HARDERIAN GLAND, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	5	5	5	5	5	4	4	4	5	5	4	4
Infiltration, Lymphocytic; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	1	1	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(1)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
HARDERIAN GLAND, RIGHT; (continued)														
minimal	0	0	0	0	0	0	0	0	0	1	0	0	1	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Inflammation, Chronic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
HEART;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	3	4	4	5	5	3	5	5	5	5	4	5	5
Infiltration; lymphohistiocytic; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(1)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	1	1	0	0	1	0	0	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	1	0	0	0	0	0	0	0
INJECTION SITE I;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	0	0	0	0	4	0	5	0	0	0	0	1	1
Fibrosis; intramuscular / interstitial	(0)	(1)	(0)	(2)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	1	0	2	1	0	0	0	0	0	1	0	0	0
Fibrosis; intramuscular / interstitial; multifocal	(0)	(0)	(3)	(2)	(3)	(0)	(4)	(0)	(3)	(1)	(3)	(1)	(0)	(4)
minimal	0	0	3	2	3	0	4	0	3	1	3	1	0	4
Fibrosis; inter- / perimuscular	(0)	(5)	(5)	(5)	(5)	(1)	(5)	(0)	(5)	(5)	(5)	(4)	(4)	(4)
minimal	0	1	1	0	2	1	1	0	1	4	1	4	4	0
mild	0	4	4	5	3	0	4	0	4	1	4	0	0	4
Fibrosis; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation; lymphohistiocytic; intramuscular / interstitial; multifocal	(0)	(2)	(2)	(5)	(4)	(0)	(3)	(0)	(4)	(1)	(4)	(1)	(0)	(4)
minimal	0	2	2	5	3	0	1	0	4	1	2	0	0	2
mild	0	0	0	0	1	0	2	0	0	0	2	1	0	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INJECTION SITE I; (continued)														
Inflammation; lymphohistiocytic; inter- / perimuscular	(0)	(3)	(2)	(4)	(3)	(0)	(3)	(0)	(4)	(1)	(5)	(0)	(1)	(4)
minimal	0	1	2	1	2	0	0	0	2	1	1	0	1	0
mild	0	2	0	3	1	0	3	0	2	0	4	0	0	4
Inflammation; lymphohistiocytic; inter- / perimuscular; multifocal	(0)	(2)	(2)	(1)	(2)	(1)	(2)	(0)	(0)	(2)	(0)	(4)	(2)	(0)
minimal	0	2	2	0	1	1	1	0	0	2	0	2	2	0
mild	0	0	0	1	1	0	1	0	0	0	0	2	0	0
Mineralization; inter- / perimuscular; multifocal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Multinucleated Macrophages; inter- / perimuscular; multifocal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	2	0	0	0	0	0	0	0	0	0	0	0	0
INJECTION SITE II;														
Examined	(5)	(1)	(0)	(0)	(5)	(0)	(5)	(5)	(1)	(0)	(0)	(5)	(0)	(5)
Within Normal Limits	5	1	0	0	0	0	0	5	0	0	0	1	0	1
Fibrosis; inter- / perimuscular	(0)	(0)	(0)	(0)	(5)	(0)	(5)	(0)	(1)	(0)	(0)	(3)	(0)	(4)
minimal	0	0	0	0	2	0	2	0	1	0	0	2	0	3
mild	0	0	0	0	3	0	3	0	0	0	0	1	0	1
Fibrosis; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Fibrosis; intramuscular / interstitial	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Fibrosis; intramuscular / interstitial; multifocal	(0)	(0)	(0)	(0)	(3)	(0)	(4)	(0)	(0)	(0)	(0)	(1)	(0)	(2)
minimal	0	0	0	0	2	0	4	0	0	0	0	1	0	2
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Fibrosis; dermis; subcutis; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INJECTION SITE II; (continued)														
Inflammation; lymphohistiocytic; inter- / perimuscular	(0)	(0)	(0)	(0)	(3)	(0)	(4)	(0)	(0)	(0)	(0)	(1)	(0)	(4)
minimal	0	0	0	0	2	0	2	0	0	0	0	0	0	1
mild	0	0	0	0	1	0	2	0	0	0	0	1	0	3
Inflammation; lymphohistiocytic; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
minimal	0	0	0	0	1	0	1	0	0	0	0	1	0	0
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation; lymphohistiocytic; intramuscular / interstitial; multifocal	(0)	(0)	(0)	(0)	(5)	(0)	(4)	(0)	(0)	(0)	(0)	(2)	(0)	(3)
minimal	0	0	0	0	3	0	2	0	0	0	0	0	0	0
mild	0	0	0	0	2	0	2	0	0	0	0	2	0	3
INTESTINE, CECUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	4	5	5	5	5	5	5	4	4	4	5	5	5
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0
mild	1	1	0	0	0	0	0	0	0	1	0	0	0	0
moderate	0	0	0	0	0	0	0	0	1	0	0	0	0	0
INTESTINE, COLON;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	1	5	3	5	5	5	5	4	5	5	4	4
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(1)	(4)	(0)	(2)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)
mild	0	1	3	0	2	0	0	0	0	1	0	0	1	0
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INTESTINE, DUODENUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
INTESTINE, ILEUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
INTESTINE, JEJUNUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
INTESTINE, RECTUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	3	3	5	3	4	3	3	4	5	4	5	5	3
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	1	0	0	1	0	0	0	0	0	1
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(2)	(2)	(0)	(2)	(1)	(2)	(0)	(1)	(0)	(1)	(0)	(0)	(1)
minimal	0	1	0	0	0	0	1	0	1	0	0	0	0	0
mild	1	1	1	0	2	1	1	0	0	0	1	0	0	1
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Nematodiasis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
KIDNEY, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Congestion	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)
mild	1	0	0	0	0	0	0	1	0	0	0	1	0	1
moderate	4	5	5	5	5	5	5	4	5	5	4	4	5	4
Basophilia; tubule; focal	(1)	(0)	(1)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	1	0	1	0	0	0	0	0	0
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(1)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
KIDNEY, LEFT; (continued)														
minimal	0	0	0	0	0	0	1	0	1	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(2)	(0)	(1)	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	1	1	1	0	0	0	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Cast; hyaline; tubule; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Degeneration; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
KIDNEY, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	(4)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
mild	1	0	1	0	0	0	0	1	1	0	0	1	0	2
moderate	3	5	4	5	5	5	5	4	4	5	5	4	5	3
Basophilia; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	2	0	0	0	1	0	0	0
Basophilia; tubule; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	1	1	0
Infiltration, Lymphocytic; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	1	0	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(1)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	1	0	1	1	0	0	0
Mineralization; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Pyelonephritis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Inflammation, Chronic; interstitial; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LACRIMAL GLAND, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
LACRIMAL GLAND, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
LIVER;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Congestion	(5)	(5)	(4)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
mild	2	1	0	0	0	1	0	1	2	3	0	1	1	3
moderate	3	4	4	5	5	3	5	4	3	2	5	4	4	2
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Necrosis; focal	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
marked	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(4)	(5)	(5)	(4)	(4)	(2)	(2)	(2)	(3)	(4)	(2)	(2)	(4)	(0)
minimal	4	5	5	4	4	2	2	2	3	4	2	2	4	0
Vacuolation; hepatocellular; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Vacuolation; hepatocellular; periportal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	1	0
LUNGS WITH BRONCHI;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	1	1	3	1	2	1	2	3	1	4	2	3	5	2
Ossification; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Hemorrhage; acute; focal	(0)	(1)	(0)	(0)	(0)	(1)	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LUNGS WITH BRONCHI; (continued)														
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
mild	0	0	0	0	0	1	0	0	1	0	0	0	0	0
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage; acute; multifocal	(0)	(0)	(0)	(2)	(1)	(2)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	2	0	0	0	0	0	0	0
mild	0	0	0	2	1	2	0	0	1	0	0	0	0	0
Hyperplasia; bronchial-associated lymphoid tissue	(3)	(3)	(2)	(3)	(2)	(3)	(1)	(1)	(2)	(0)	(3)	(1)	(0)	(1)
minimal	3	3	2	2	2	3	1	1	2	0	3	1	0	1
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration, Eosinophilic; perivascular ; multifocal	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(2)
minimal	1	1	0	0	0	0	0	0	0	1	0	0	0	2
Infiltration; macrophage; alveolus; focal	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; mixed; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Pigmentation; brown; macrophage; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
LYMPH NODE, CERVICAL;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Histocytosis	(5)	(5)	(5)	(3)	(5)	(5)	(5)	(5)	(4)	(5)	(4)	(5)	(5)	(4)
minimal	5	5	4	1	4	3	3	5	1	1	3	2	5	3
mild	0	0	1	2	1	2	2	0	3	4	1	3	0	1
Pigmentation; brown; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Increased Cellularity; germinal center	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
minimal	0	1	0	0	2	2	0	2	0	0	0	0	1	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, CERVICAL; (continued)														
mild	4	3	5	5	3	3	5	3	5	4	4	5	4	4
moderate	1	1	0	0	0	0	0	0	0	1	1	0	0	0
LYMPH NODE, ILIAC;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Histocytosis	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(3)	(5)	(5)	(4)
minimal	3	2	2	3	1	2	4	5	4	4	2	1	3	3
mild	2	3	3	2	3	2	1	0	1	1	1	4	2	1
moderate	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Plasmacytosis	(0)	(0)	(0)	(2)	(3)	(0)	(1)	(0)	(3)	(3)	(3)	(5)	(1)	(4)
minimal	0	0	0	2	2	0	1	0	2	2	3	2	1	1
mild	0	0	0	0	1	0	0	0	1	1	0	3	0	3
Infiltration; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration; macrophage; multifocal	(0)	(0)	(1)	(1)	(5)	(3)	(5)	(0)	(3)	(0)	(3)	(5)	(4)	(4)
minimal	0	0	1	1	0	2	4	0	3	0	2	2	4	0
mild	0	0	0	0	5	1	1	0	0	0	1	2	0	3
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Increased Cellularity; germinal center	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(4)	(4)
minimal	1	3	1	3	1	4	1	2	2	1	1	0	3	0
mild	4	1	4	1	4	1	4	2	3	3	4	3	1	3
moderate	0	1	0	1	0	0	0	0	0	1	0	2	0	1
LYMPH NODE, MESENTERIC;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Erythrophagocytosis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Histocytosis	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)
minimal	3	2	1	1	0	3	0	2	0	1	0	0	1	1
mild	2	3	4	4	5	2	5	2	5	4	5	5	4	4
Pigmentation; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, MESENTERIC; (continued)														
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Increased Cellularity; germinal center	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(3)
minimal	0	0	0	0	0	2	0	0	0	0	0	1	1	0
mild	5	5	5	5	5	2	5	5	5	5	5	3	4	3
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0
MAMMARY GLANDS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SKELETAL MUSCLE;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	4	5	5	5	4
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
NERVE, SCIATIC;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)
Within Normal Limits	5	5	5	5	5	5	3	5	5	5	5	4	4	4
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Inflammation; perineural	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(1)	(0)	(1)
minimal	0	0	0	0	0	0	2	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
OPTIC NERVE, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	5	5	5	5	5	4	5	4	5	5	5	5
Not Examined: INSUFFICIENT TISSUE TO EVALUATE	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	1	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
OPTIC NERVE, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	4	4	5	5	5	5	5	5	5	5	5	5
Pigmentation; brown; macrophage; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage; acute; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration; foamy; macrophage	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
OVARY, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	5	5	5
OVARY, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	5	5	5
OVIDUCT, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	5	5	5
OVIDUCT, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(4)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	4	5	5
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	1	0	0
PANCREAS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	4	5	5	5
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0
PARATHYROID, LEFT;														
Examined	(2)	(2)	(3)	(5)	(5)	(4)	(4)	(4)	(5)	(1)	(4)	(3)	(4)	(5)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PARATHYROID, LEFT; (continued)														
Within Normal Limits	2	2	3	5	5	4	4	4	5	1	4	3	4	5
Not Examined: NOT PRESENT	3	3	2	0	0	1	1	1	0	4	1	2	1	0
PARATHYROID, RIGHT;														
Examined	(4)	(3)	(4)	(3)	(4)	(5)	(5)	(3)	(5)	(4)	(4)	(2)	(4)	(4)
Within Normal Limits	4	3	4	3	4	5	5	3	5	4	4	2	4	4
Not Examined: NO SECTION	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Not Examined: NOT PRESENT	1	2	1	2	1	0	0	1	0	1	1	3	1	1
PEYERS PATCHES;														
Examined	(4)	(3)	(4)	(5)	(5)	(4)	(3)	(5)	(5)	(5)	(5)	(4)	(4)	(5)
Within Normal Limits	0	0	0	0	0	1	0	0	0	0	2	0	0	1
Not Examined: NOT PRESENT	1	2	1	0	0	1	2	0	0	0	0	1	1	0
Mineralization; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Mineralization; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	1	0	0
Inflammation, Granulomatous; follicular; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	1	0	0	0
Inflammation, Granulomatous; follicular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Increased Cellularity; germinal center	(4)	(3)	(4)	(5)	(5)	(3)	(3)	(5)	(5)	(5)	(3)	(4)	(4)	(4)
mild	0	2	1	1	0	1	1	2	0	1	0	0	0	0
moderate	4	1	3	4	5	2	2	3	5	4	3	4	4	4
PITUITARY GLAND;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	4	5	5	5	5	5	5	5	4	5	5	5	5
Cyst; pars distalis; few	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Cyst; pars intermedia	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PITUITARY GLAND; (continued)														
minimal	1	0	0	0	0	0	0	0	0	1	0	0	0	0
PROSTATE GLAND;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	5	4	2	1	4	2	3	-	-	-	-	-	-	-
Inflammation; purulent; focal	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	1	1	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; widespread	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	0	0	1	0	0	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(1)	(2)	(1)	(0)	(0)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	1	1	0	0	0	-	-	-	-	-	-	-
mild	0	1	0	0	0	0	0	-	-	-	-	-	-	-
moderate	0	0	1	0	0	0	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(0)	(0)	(1)	(2)	(0)	(2)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	1	1	0	2	0	-	-	-	-	-	-	-
mild	0	0	0	1	0	0	1	-	-	-	-	-	-	-
SALIVARY GLANDS, MANDIBULAR;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SALIVARY GLANDS, SUBLINGUAL;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	4
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
SALIVARY GLANDS, PAROTIS;														
Examined	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	4	5	5	5	5	5	5	5	5	5
Not Examined: NOT PRESENT	0	0	0	0	1	0	0	0	0	0	0	0	0	0
SEMINAL VESICLES;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	5	4	5	5	5	5	5	-	-	-	-	-	-	-

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SEMINAL VESICLES; (continued)														
Infiltration, Lymphocytic; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	1	0	0	0	0	0	-	-	-	-	-	-	-
SKIN;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SPINAL CORD;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SPLEEN;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	2	1	3	3	3	3	3	3	2	1	2	3	0	2
Congestion	(3)	(4)	(2)	(2)	(2)	(2)	(2)	(2)	(3)	(4)	(3)	(2)	(5)	(3)
minimal	1	3	1	2	2	2	2	2	2	2	2	2	4	3
mild	2	1	1	0	0	0	0	0	1	2	1	0	1	0
STOMACH, GLANDULAR;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	2	1	1	0	1	0	1	0	0	1	2
Infiltration, Eosinophilic	(5)	(5)	(5)	(3)	(4)	(4)	(5)	(4)	(5)	(4)	(5)	(5)	(4)	(3)
minimal	4	3	2	2	3	3	5	4	5	4	5	5	4	1
mild	1	2	3	1	1	1	0	0	0	0	0	0	0	2
Dilation; glandular; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	1	0	0
Dilation; glandular; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	1
Cyst; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	1	0	0	0	0
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	1	0	0	0	0

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
STOMACH, NONGLANDULAR;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
TESTIS, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	3	5	5	4	5	5	5	-	-	-	-	-	-	-
Spermatid Giant Cells; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	1	0	0	0	0	0	0	-	-	-	-	-	-	-
Dilation; tubular	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	1	0	0	1	0	0	0	-	-	-	-	-	-	-
TESTIS, RIGHT;														
Examined	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	4	4	5	4	5	5	5	-	-	-	-	-	-	-
Not Examined: NOT PRESENT	0	1	0	0	0	0	0	-	-	-	-	-	-	-
Dilation; tubular	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
moderate	1	0	0	1	0	0	0	-	-	-	-	-	-	-
Infiltration; lymphoplasmacytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
moderate	1	0	0	0	0	0	0	-	-	-	-	-	-	-
Spermatocoele; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	1	0	0	0	0	0	0	-	-	-	-	-	-	-
THYMUS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	3	4	3	4	3	2	3	4	3	4	3	5	3	4
Hemorrhage; acute; focal	(1)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
minimal	1	0	0	0	0	2	0	0	1	0	0	0	1	0
Hemorrhage; acute; multifocal	(1)	(1)	(2)	(1)	(2)	(1)	(2)	(1)	(1)	(1)	(2)	(0)	(1)	(1)
minimal	1	0	1	1	2	1	2	0	1	1	2	0	0	1
mild	0	1	1	0	0	0	0	1	0	0	0	0	1	0
THYROID, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)
Within Normal Limits	4	5	5	5	5	5	5	5	5	4	5	5	5	5

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
THYROID, LEFT; (continued)														
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Cyst; keratinized; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
THYROID, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	4	5	5	5	4	5
Cyst; keratinized; multiple	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Cyst; keratinized; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
TONGUE;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	4	5	5	5	5	5	5	5	5	5	4	5
Granuloma; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Granuloma; hair; single	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
TRACHEA;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	5	4	5	5	5	5	4	4	5	5	5	4
Infiltration; lymphohistiocytic;														
multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	1	0	0	0	0
URINARY BLADDER;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	4	5	5	5	5	5	5

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
URINARY BLADDER; (continued)														
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
UTERUS;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	4	5	4	5	5
Dilation	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
mild	-	-	-	-	-	-	-	0	0	1	0	0	0	0
moderate	-	-	-	-	-	-	-	0	0	0	0	1	0	0
VAGINA;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	4	2	3	1	1	3	2
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(1)	(3)	(2)	(4)	(4)	(2)	(3)
minimal	-	-	-	-	-	-	-	0	2	1	1	0	0	2
mild	-	-	-	-	-	-	-	1	1	1	3	4	2	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		+	N	N	N	N	N	N	N	N	N	N	N	N	+	N
Dilation; vascular		1	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	+	N	N	N	N	+	N	N
Dilation; vascular		.	.	.	.	.	.	.	1	.	.	.	.	1	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		+	+	+	N	+	+	+	N	N	+	N	+	+	+	+
Infiltration, Lymphocytic		1	1	1	.	1	1	1	.	.	1	.	1	1	1	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	N	N	+	+	N	+	+	+	N	N	+	+	+
Infiltration, Lymphocytic		1	1	.	.	1	1	.	1	1	1	.	.	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	+	N	N	+	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	1	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	N	N	N	N	+	+	+	+	+	N	N	N	N	N
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		1	.	.	.	.	1	1	1	1	1	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	N	N	N	+	+	+	N	N	N	N	N	N	N
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		2	.	.	.	.	.	.	.	.	1	1	1	.	.	.
Inflammation; mixed		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	2	.	.	.	.	
INTESTINE, COLON;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	3	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	+	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	2	.	.	.	.	.	2	.	.	.		
KIDNEY, LEFT;		+	+	+	N	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	.	3	3	3	2	3	3	3	3	2	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	1	.	.	.	.	1	1
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	2	.	.	.	.	.	.	1
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	N	+	+	+	+	
Congestion		2	3	3	3	3	3	2	2	3	3	.	3	2	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	2	3	3	3	2	3	2	3	3	3	2
Hematopoiesis; extramedullary		.	.	.	.	.	1	.	.	1	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	2	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration, Lymphocytic		.	1	1	.	.	1	1	.	.	1	1	1	1	1	.
Vacuolation; hepatocellular		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	N	+	+	+	+	+	+	+	+	N	+	
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	1	.	.	2	1	.	.	2	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	.	.	.	.	1	1	1	.	1	1	1	.	.
perivascular; Infiltration, Eosinophilic		.	.	1	.	1	.	.	.	.	.	.	.	.	.	1
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	X	+	+	X	+	+	+	+	+	+	+
Histocytosis		1	1	1	1	.	1	1	.	1	1	1	1	1	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	1	.	1	1	.	1	2	2	3	2	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	1	1	2	2	2	2	2	1	1	2	1	1	2
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	1	1	2	1	.	2	.	1	2	2	2	1	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	1	2	1	2	1	1	1	2	1	1	1	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	1	2	.	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	X	N	X	X	N	X	N	N	N	X	N	X	N	X
PARATHYROID, RIGHT;		N	N	N	X	N	N	N	N	N	N	N	X	N	N	N
PEYERS PATCHES;		+	+	+	+	N	X	+	+	X	+	+	+	+	X	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
germinal center; Increased Cellularity		3	3	3	3	.	.	3	3	.	3	3	3	3	.	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	+	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
PROSTATE GLAND;		N	N	N	N	N	+	+	N	+	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	2	.	2	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	N	+	+	+	+	+	+	+	+	+	N	+	N	
Congestion		1	.	1	1	1	1	1	1	1	1	2	1	.	2	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	N	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	2	1	2	1	2	1	.	3	2	1	2	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
THYMUS;		+	N	N	N	+	N	N	N	+	N	+	N	N	N	+
Hemorrhage; acute		1	.	.	.	1	.	.	.	1	.	1	.	.	.	1
THYROID, LEFT;		N	N	N	N	N	N	N	+	N	N	N	+	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	1	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	+	+	+	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	1	.	.	1	.	1	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	+	N	+	+	N
Dilation; vascular		.	.	.	.	.	.	.	.	1	.	1	.	1	1	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	+	N	N	N	N	N	N	+	+	N	N	N	
Dilation; vascular		.	.	1	.	.	.	.	.	.	1	1	.	.	.	
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
AORTA ABDOMINALIS;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
EPIDIDYMIS, LEFT;		+	+	+	+	+	N	+	N	+	+	+	+	+	+	
Infiltration, Lymphocytic		1	1	1	1	1	.	1	.	1	1	1	1	1	1	

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	+	+	+	+	N	+	+	+	+	N	+	+	+
Infiltration, Lymphocytic		1	1	1	1	1	1	.	1	1	1	1	.	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HEART;		+	N	N	N	N	N	N	N	N	+	N	+	N	N	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	.	.	.	1	.	.	
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	3	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		2	2	3	3	3	3	3	3	.	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	.	2	1	1	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	.	3	.	3	3	.	.	2	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	1	2	2	.	2	2	2	.	.	1	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	.	1	.	.
intramuscular / interstitial; Inflammation; mixed		3	2	3	.	3	2	1	2	2	3	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	1	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	2	3	2	3	3	2	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	1	1	1
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	1	2	.	.	.
inter- / perimuscular; Edema		3	2	3	.	3	3	.	.	2	4	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	2	2	.	.	.
epidermis; Ulceration		.	.	.	.	.	2	.	3	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	+	.	+	.	.	+	.	+	.	.	N	.	.	.
Hyperplasia; epidermal		.	3	.	3	.	.	3	.	3	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	2	.	2	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)															
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	2	.	.	2	.	2	.	.	.	.	.
myofiber; Necrosis		.	.	.	1	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	1	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	2	.	.	.	.	.
subcutis; Edema		.	2	.	3	.	.	3	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	2	.	3	.	.	3	.	3	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	2	.	.	3	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	2	.	2	.	.	2	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	2	.	3	.	.	3	.	1	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	2	.	2	.	.	2	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	1	.	3	.	.	2	.	2	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	3	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	2
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	N	+	N	+	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	2	.	1	.	.	2
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	2	3	3	3	2	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	2	3	3	3	2	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	N	+	+	+	+	+	+	+	+
Congestion		3	3	2	2	2	3	.	3	2	2	3	3	3	3	2
Hematopoiesis; extramedullary		.	.	1	1	1	1	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	+	+	+	+	N	N	N	+	+	+	+	N	+	+
Ossification		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	2	1	.	.	.	.	.	.	.	.	.	3	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	1	1	1	.	.	.	1	1	1	.	.	1	1
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	2	1	1	1	1	2	1	1	1	1	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	1	1	2	1	2	2	2	2	2	3	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		.	1	1	2	1	1	2	2	2	1	2	1	1	2	2
Plasmacytosis		2	.	2	1	1	.	.	.	2	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	1	1	1	.	1	2	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	2	2	3	1	.	2	1	1	1	1	3	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	2	2	1	2	1	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	+	N	+	N	N	N	N	+	N	N	N	N	N	N
perineural; Inflammation		.	3	.	3	.	.	.	.	4	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
OPTIC NERVE, RIGHT;		N	N	N	X	N	N	N	N	X	X	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	X	X	N	N	
PARATHYROID, RIGHT;		N	X	N	X	N	N	N	X	N	N	X	N	X	N	N
PEYERS PATCHES;		+	X	+	+	X	+	X	N	X	+	X	+	+	X	+
Mineralization		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	.	2	2	.	3	.	.	.	2	.	2	3	.	2
PITUITARY GLAND;		N	N	+	N	N	N	N	N	N	N	N	N	N	+	N
pars distalis; Cyst		.	.	1	.	.	.	.	.	.	.	.	.	2	.	
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
PROSTATE GLAND;		N	N	N	N	+	X	N	N	N	N	N	N	N	+	N
Infiltration; mixed		.	.	.	.	2	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	2	.	

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	+	+	+	+	+	+	+	+	+	+	+	N	+	+
Congestion		1	1	1	1	1	1	2	1	1	1	1	2	.	1	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	1	1	1	1	.	1	1	1	1	2	1	1	2	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		1	.	.	.	.	1	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	X	N	
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	+	+	+	N	N	+	+	+	N	N	N	N	+	N
Hemorrhage; acute		1	2	1	1	.	.	1	1	2	.	.	.	.	2	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	+	+	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	1	1	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	+	N	+	N	+	N	+	N	N	+	N	N	N
Dilation; vascular		.	.	1	.	1	.	1	.	1	.	.	1	.	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	+	+	+	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		.	1	1	1	.	.	.	.	.	.	.	.	.	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		+	+	+	+	N	+	+	+	+	+	+	+	N	+
Infiltration, Lymphocytic		1	1	1	1	.	1	1	1	1	2	1	1	.	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	N	+	N	+	+	+	N	+	+	+	+	+	+
Infiltration, Lymphocytic		1	1	.	1	.	1	1	1	.	1	1	1	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
HEART;		+	N	N	N	N	N	N	N	N	N	N	+	N	N	
Infiltration; lymphohistiocytic		3	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		.	2	3	2	3	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	.	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	3	3	3	3	3	3	2	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	1	1	1	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1	1
intramuscular / interstitial; Inflammation; mixed		2	2	2	2	2	3	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		.	1	1	1	1	2	1	1	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		2	2	2	3	3	3	3	3	2	2	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		3	.	3	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)															
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		+	N	N	N	N	+	N	N	N	N	+	+	+	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		2	.	.	.	.	1	.	.	.	.	2	2	3	2	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	+	N	N	N	+	N	N	N	+	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	1	.	.	.	2	.	.	.	2	.	.	3
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	2	3	2	3	2	2	3	3	3	3	3	3
Infiltration, Lymphocytic		.	1	.	.	1	.	.	.	.	1	.	.	.	1	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	2	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	2	3	2	2	2	2	3	3	3	3	3	2
Infiltration, Lymphocytic		.	1	.	1	.	.	.	.	.	1	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	3	3	3	3	2	2	.	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	1	1	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	1	1	1	.	.	1	.	.	.	1	1	1	1	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	+	+	+	+	N	N	+	+	N	N	+	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	2	2	.	2	1	.	.	1	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	.	.	1	1	.	.	.	.	1	.	.	1	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	1	1	1	1	1	.	1	2	1	1	1	2	1
Hemorrhage		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	1	1	1	2	2	2	2	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	1	1	2	2	1	1	2	2	1	1	2	2
Plasmacytosis		2	2	2	2	.	1	.	2	2	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
germinal center; Increased Cellularity		2	.	3	3	3	2	2	2	2	2	2	2	2	2	1
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	1	2	2	2	2	2	2	2	1	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	X	N	X	N	N	N	N	N	N	X	N	X	N	N
PARATHYROID, RIGHT;		N	N	N	N	N	X	N	N	X	X	N	X	N	N	N
PEYERS PATCHES;		+	+	+	+	X	+	+	+	+	+	+	+	+	+	X
Mineralization		.	.	.	.	.	1	.	.	1	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	2	2	3	.	3	3	3	3	3	3	3	3	2	.
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	+	N	+	N	N	N	N	N	N	+	+	N	+	
Infiltration; mixed		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	2	.	.	.	.	.	.	1	3	.	1	

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	N	+	N	+	+	N	N	N	+	+	+	N	N	N
Congestion		1	.	1	.	1	1	.	.	.	.	2	1	.	.	.
Hematopoiesis; increased		1	.	.	.	1	.	.	.	.	1	.	.	.	.	.
STOMACH, GLANDULAR;		N	N	+	N	+	+	+	N	N	+	+	+	+	+	+
Infiltration, Eosinophilic		.	.	1	.	1	.	1	.	.	1	2	1	2	2	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	1	.	.	.	.	.	.	.	1
Cyst		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	N	N	+	+	+	N	N	+	+	+	N	+	N	N
Hemorrhage; acute		1	.	.	1	1	1	.	.	1	1	2	.	1	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
TRACHEA;		N	N	+	N	+	N	N	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	1	.	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE															
	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	N	+	N	N	N	N	N	N	+	+	+	N	N
Dilation; vascular		.	.	.	1	.	.	.	.	.	.	1	1	1	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	N	N	+	N	+	+	N	N	+	+	+	N	+	
Infiltration, Lymphocytic		.	.	.	.	1	.	1	1	.	.	1	1	1	.	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL										1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		N	+	N	N	+	+	+	+	+	N	+	+	+	+	N
Infiltration, Lymphocytic		.	1	.	.	1	1	.	1	1	.	1	1	1	1	.
Infiltration; mixed		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	+	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	.	.	1	.	.	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	+	N	N	N	N	+	N	+	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		3	3	2	2	2	2	.	2	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	.	2	2	1	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		4	3	3	3	3	3	2	3	4	3	.	.	.	.	.
subcutis; Edema		3	3	3	2	2	2	.	2	4	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	.	2	2	2	.	1	1	1	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
intramuscular / interstitial; Inflammation; mixed		3	3	3	3	3	3	2	3	3	3	.	.	.	.	.
intramuscular / interstitial; Edema		2	1	1	2	2	2	.	.	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	.	2	2	2	2	2	2	2	2
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		4	3	4	3	3	3	2	3	4	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	2	2	1
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		3	3	3	2	2	3	.	#	4	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	3	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL										1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	+	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	2	.	.	2	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	+	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	2	.	.	2	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	+	N	N	+	N	N	N	N	N	
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	1	.	.	2	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	2	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	.	1	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	1	.	1	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	2	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	3	3	3	3	2	3	3	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	1	1	1	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		2	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Infiltration, Neutrophilic		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	.	1	1	.	.	.	1	.	.	1	1	1	1	.
Vacuolation; hepatocellular		2	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration, Eosinophilic		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	+	+	N	+	+	+	+	+	N	+	+	
Ossification		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	1	1	1	.	.	.	.	.	2	.	.	2	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	1	.	1	1	.	1	1	1	2	1	.	.	1
perivascular; Infiltration, Eosinophilic		.	.	.	.	1	.	.	.	2	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	1	1	1	1	2	1	2	1	2	.	.	1	2
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	1	1	1	1	1	2	1	1	1	2	2	2	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	2	2	2	2	2	1	.	1	1	1	2	2
Plasmacytosis		3	2	2	.	3	3	3	3	3	3	1	.	1	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
germinal center; Increased Cellularity		2	2	2	1	2	2	2	2	2	2	2	1	3	1	1
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	3	2	2	2	3	2	2	1	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	1	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	3	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		X	X	X	X	X	N	X	X	X	N	N	N	N	N	N
PARATHYROID, RIGHT;		N	N	X	X	X	N	X	N	N	X	X	N	X	N	N
PEYERS PATCHES;		+	+	+	+	+	+	+	+	+	X	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	3	3	3	3	2	3	3	.	3	3	3	3	2
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	+	N	N	N	+	N	N	N	+	+	+	+
Infiltration; mixed		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Inflammation; purulent		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	2	1	2	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	+	+	+	N	+	+	+	+	+	N	+	+	N	N
Congestion		1	1	1	1	.	1	1	1	1	1	.	1	1	.	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	N	+	N	+	+
Infiltration, Eosinophilic		2	2	2	1	2	2	2	1	2	2	.	1	.	1	2
Infiltration, Lymphocytic		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	3	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	N	N	+	N	+	+	N	N	+	N	N	+	N	N
Hemorrhage; acute		1	.	.	1	.	1	1	.	.	2	.	.	1	.	.
THYROID, LEFT;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	+	N	N	N	+	+	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	1	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE															
GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;	N	+	N	N	X	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic	.	1	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	+	N	N	N	N	N	N	N	N	N	+	N	+	
Dilation; vascular		.	1	.	.	.	.	.	.	.	.	.	1	.	1	
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	
ADRENAL GLAND, RIGHT;		+	N	N	N	N	+	N	N	N	N	N	N	+	N	
Dilation; vascular		1	.	.	.	.	1	.	.	.	.	.	.	1	.	
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BONE, OS FEMORIS WITH JOINT;		+	N	N	N	+	N	+	+	N	N	+	N	N	N	
surrounding tissue; Inflammation; mixed		3	.	.	.	2	.	2	1	.	.	.	.	.	.	
surrounding tissue; Infiltration, Lymphocytic		...	.	.	.	.	.	.	.	.	.	1	.	.	.	
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	2	.	.	.	.	.	.	
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
EPIDIDYMIS, LEFT;		N	+	+	+	+	+	N	+	N	N	+	+	+	N	
Infiltration, Lymphocytic		.	1	1	1	1	1	1	.	1	.	.	1	1	1	.

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Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	+	+	+	N	+	+	+	N	+	+	N	+	N
Infiltration, Lymphocytic		1	1	1	1	1	.	1	1	1	.	1	1	.	1	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		+	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		2	3	2	2	3	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	1	2	2	2	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	2	3	3	3	2	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	.	3	3	3	.	3	3	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	.	2	2	2	1	2	2	2	1	1	1	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	1	.	1
intramuscular / interstitial; Inflammation; mixed		2	3	.	3	3	3	2	2	3	1	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	.	2	2	2	.	2	2	1	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	1	1
inter- / perimuscular; Inflammation; lymphocytic		.	.	3	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	3	1	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	1	1
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		3	3	.	3	3	3	.	3	3	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia; epidermal		3	3	2	3	3	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		4	2	2	4	4	3	2	3	3	3	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	2	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Edema		4	3	3	3	4	4	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	2	2	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	1	1	1
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	1	1	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	1	1	1
intramuscular / interstitial; Inflammation; mixed		2	3	2	3	3	2	2	2	3	3	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		+	+	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		1	1	.	.	1	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		+	+	N	N	+	N	N	N	N	N	N	+	N	N	+
Infiltration, Eosinophilic; increased		1	1	.	.	1	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		2	.	.	.	.	.	.	.	.	.	2	.	.	2	

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		+	+	N	N	+	N	N	N	+	N	N	+	+	N	N
Infiltration, Eosinophilic; increased		1	1	.	.	1	.	.	.	.	.	.	.	1	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	2	.	.	2	2	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	3	3	3	2	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	3	2	2	3	2	3	3	3	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	1	1	.	.	.	.	.	.	1	1	1	.	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		1	1	2	1	.	1	.	2	2	1	.	.	.	.	.
kupffer cell; Pigmentation; brown		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		N	N	+	+	+	+	+	+	N	+	N	+	+	+	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	1	.	.	1	.	.	.	2	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	.	1	1	1	.	.	1	.	.	1	1	.
perivascular; Infiltration, Eosinophilic		.	.	1	1	.	1	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	1	2	1	1	1	2	2	2	1	1	1	2	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	2	2	1	2	2	2	2	2	2	1	2	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	1	1	2	2	2	2	2	2	1	2	2	2	3
Plasmacytosis		1	2	3	4	.	.	2	2	3	2	1	1	.	.	2
Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	2	.	.	3	.	2	2	3	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	2	2	2	2	2
germinal center; Increased Cellularity		2	1	2	2	2	2	2	2	3	3	2	2	2	1	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	1	2	2	2	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		+	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	+	N	N	N	N	N	+	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	3	.	.	.	.	.	2	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	N	+	N	+	N	+	N	N	N	N	N
perineural; Inflammation		1	1	2	1	.	3	.	3	.	2	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		+	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
PARATHYROID, RIGHT;		N	N	X	N	N	N	N	X	N	X	N	N	N	N	X
PEYERS PATCHES;		+	+	+	+	+	+	N	+	+	+	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	3	2	3	3	.	3	3	3	3	3	3	3	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	N	N	N	+	N	X	N	N	N	+	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	X	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	3	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	+	+	+	+	+	N	+	N	+	N	N	+	+	N
Congestion		.	1	1	1	1	.	.	1	.	1	.	.	1	1	.
Hematopoiesis; increased		2	.	.	.	.	2	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	N	+	+	+	
Infiltration, Eosinophilic		2	1	1	1	2	1	2	1	1	1	2	.	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	+	N	N	+	+	N	N	N	N	N	+	N	N	+
Hemorrhage; acute		1	2	.	.	2	1	.	.	.	.	.	1	.	.	1
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		+	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		1	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE															
GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	+
Dilation; vascular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	1
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	+
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	1	.	1
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	X	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	N	+	+	+	+	+	N	+	N	N	+	+	+	+
Infiltration, Lymphocytic		.	.	1	1	1	1	1	.	1	.	.	1	1	1	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		N	N	+	+	+	+	+	+	N	N	+	+	+	+	+
Infiltration, Lymphocytic		.	.	1	1	1	1	1	1	.	.	1	1	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		+	N	+	N	N	N	N	N	+	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Infiltration; mixed		1	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	N	+	+	+	+	+	N	N	N	N	
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
myofiber; Necrosis		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	.	3	.	2	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	3	4	.	3	4	3	4	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	.	2	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		3	2	2	3	.	3	3	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	.	1	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	.	2	2	3	2	2	1	.	.	.	.
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		3	3	3	#	.	2	3	2	4	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	+	+	N	+	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	1	2	.	2	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	N	N	N	+	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	2	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	2	.	.	1	.	.	.	.	1	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	1	.	.	.	.	.	.	2	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	N	+	+
Congestion		3	2	2	3	2	2	3	3	3	3	3	3	.	2	3
Hematopoiesis; extramedullary		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	1	.	.	.	.	.	.	1	.	.	.	.
Necrosis		.	1	.	.	.	.	.	.	.	4	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	1	
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	+	N	N	+	N	+	+	+	N	+	N	+	+	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	2	.	.	2	.	2	.	2
Infiltration; lymphohistiocytic		.	.	.	.	2	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	.	.	.	.	1	.	1	.	1	.	1	1	.
perivascular; Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	.	2	1	1	2	2	1	1	1	1	2	2	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	1	2	2	2	1	2	1	1	2	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	2	2	2	2	1	2	2	1	2	.	2	1	1
Plasmacytosis		1	.	.	1	1	1	.	2	.	3	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	3	.	2	3	1	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	2	.	1	.
germinal center; Increased Cellularity		2	2	2	3	2	3	2	2	2	2	1	2	1	1	1
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		3	2	2	2	2	2	2	2	2	2	2	2	1	1	1
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	1	2	2	2	2	2	2	1	2	3	1	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		+	N	+	N	N	N	N	+	+	N	N	N	N	N	N
interstitium; Inflammation; mixed		3	.	2	.	.	.	.	2	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	3	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	X	N	N	X	N	N	N	X	N
PARATHYROID, RIGHT;		N	N	N	N	N	N	X	X	X	N	N	N	N	N	N
PEYERS PATCHES;		+	+	+	+	+	+	+	+	+	+	N	+	+	X	+
Mineralization		.	.	.	.	.	.	1	1	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	2	2	3	3	2	2	3	3	.	3	3	.	2
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	N	N	+	N	N	N	N	+	N	+	+	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	2	.	.	.	.	1	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	1	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	N	N	+	N	+	N	+	N	+	N	N	N	+	+
Congestion		1	.	.	2	.	1	.	1	.	1	.	.	.	1	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	N	+	N	+	+	N	+	N	+	+	+	+	N
Infiltration, Eosinophilic		1	1	.	1	.	1	.	.	1	.	2	1	1	1	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		N	N	N	+	+	N	N	+	+	+	+	+	N	+	N
Hemorrhage; acute		.	.	.	1	1	.	.	2	1	1	1	1	.	1	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE															
GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	+	N	N	N	N	N	+	N	N	N	N	+	N	+
Dilation; vascular		.	1	.	.	.	.	.	.	.	.	.	.	1	.	1
Vacuolation; cortical		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	+	N	N	N	+	N	N	+	N	+	N	N
Dilation; vascular		.	.	.	1	.	.	.	.	.	.	1	.	1	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	+	N	N	N	+	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	2	.	.	.	2	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	+	+	+	+	+	+	+	+	+	N	N	+	+	N
Infiltration, Lymphocytic		.	1	1	1	1	1	1	1	1	1	.	.	1	1	.

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Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	+	+	+	+	+	+	+	+	N	+	+	N	
Infiltration, Lymphocytic		1	1	1	1	1	1	1	1	1	1	.	1	1	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
HARDERIAN GLAND, LEFT;		+	N	N	N	N	N	N	N	N	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; lymphohistiocytic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HEART;		N	N	N	N	N	N	N	N	N	N	+	+	N	N	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	1	.	.	
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Hemorrhage		.	.	.	2	.	.	.	.	.	.	.	.	.	.	
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)															
Hyperplasia; epidermal		3	.	3	2	2	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		4	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	2	3	3	3	3	4	4	3	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	.	1	1	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	1	2
intramuscular / interstitial; Inflammation; mixed		3	2	3	2	3	3	3	2	2	3	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	1	2	2	2
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		4	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	2	2
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		4	3	3	3	3	3	4	4	4	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia; epidermal		3	.	3	2	3	.	3	3	3	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)															
Hemorrhage		.	.	.	.	.	.	.	.	2	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		4	3	3	3	4	3	4	3	3	#	.	.	.	.
subcutis; Fibrosis		2	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Edema		4	4	3	3	4	3	4	3	4	2	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	2	1	2
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	2	1	2
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	1	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	2	2	2	2	2	2	2	2	2	1	1	1	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	2	.	2
intramuscular / interstitial; Inflammation; mixed		2	2	3	3	3	3	2	3	3	2	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	1	2
KIDNEY, LEFT;		+	+	+	+	+	N	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	.	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	1	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	1	1	.	.	.	.	.	.
tubule; Cast; hyaline		.	1	1	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	2	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	1	1	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	2	2	.	.	.	.	.	.	1	1	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	3	3	3	3	3	2	2	3	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	1	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	1	1	.	.	.	1	.	.	.	.	1	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	1	2	1	2	2	1	1	1	2	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	N	N	N	+	+	N	+	+	+	N	+	N	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		2	.	.	.	.	.	2	.	.	2	1	.	.	.	1
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	.	.	1	.	.	1	.	.	.	1	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	N	+	+	+	+	+	+
Histocytosis		1	1	1	2	2	2	1	.	.	2	2	1	2	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	3	3	1	3	.	2	2	2	2	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	.	2	2	1	2	1	2	2	1	1	1	1	2
Plasmacytosis		2	2	2	2	2	3	2	2	2	2	1	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	2	2	1	2	2	2	2	3	2	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	1	1	1	2
germinal center; Increased Cellularity		3	2	2	2	2	2	2	2	3	2	1	2	2	2	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	3	2	2	2	2	2	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	+	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	+	N	N	+	N	+	+	N	+	N	N	N	N	N
Infiltration; mixed		.	1	.	.	1	.	1	1	.	1	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	1	1	.	1	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	+	+	+	+	+	+	N	N	N	+	+
perineural; Inflammation		3	3	2	4	3	3	1	4	3	2	.	.	.	1	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	X	N	N	X	X	N	N	N	N	X	N	N	N	N
PARATHYROID, RIGHT;		N	N	N	X	X	N	N	N	X	N	N	N	N	N	N
PEYERS PATCHES;		+	+	+	+	+	+	+	X	+	+	+	X	+	+	X
Mineralization		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	3	3	2	3	3	.	2	3	3	.	3	2	.
PITUITARY GLAND;		N	N	+	N	+	+	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	1	.	1	2	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	2	3

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		N	N	+	N	N	+	N	+	+	+	+	+	N	N	N
Congestion		.	.	1	.	.	1	.	1	1	.	1	1	.	.	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	1	1	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	1	1	1	1	1	.	1	1	1	1	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	2	.	.	.	.	.	.	.	.	.	2
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		N	+	+	+	N	+	N	N	+	N	+	+	N	N	N
Hemorrhage; acute		.	2	2	1	.	1	.	.	1	.	1	1	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE															
GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	+	N	+	+	
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	1	.	1	1	
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
ADRENAL GLAND, RIGHT;		N	N	N	N	N	+	N	N	N	+	N	N	N	N	
Dilation; vascular		.	.	.	.	.	1	.	.	.	1	.	.	.	.	
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
BONE MARROW, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
CERVIX;		+	N	+	N	N	N	N	N	N	N	+	N	N	N	
Keratinization; epithelial		2	.	2	.	.	.	.	.	.	.	2	.	.	.	
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	N	+	N	N	N	N	+	N	N	N	N	N
Hemorrhage		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		1	.	1	.	.	.	.	.	.	1	.	.	.	.	.
Inflammation; mixed		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Inflammation;																
lymphohistiocytic		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;																
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;																
mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation;																
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		N	+	N	N	+	+	+	N	N	+	N	N	N	N	N
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	1	1	1	.	.	1	.	.	.	.	.
Inflammation; mixed		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	N	N	N	N	+	N	N	N	N	+	N	+	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	3	3	2	3	3	2	3	3	2	3	3
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	1	.	.	.	.	1	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	3	3	2	3	3	2	3	3	2	3	3
Infiltration, Lymphocytic		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
pelvis; Inflammation; purulent		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	3	3	3	2	3	1	2	2	3	3	2	3	3
Hematopoiesis; extramedullary		.	1	.	.	1	.	.	.	1	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	1	1	1	.	1	1	1	.	.	1	1	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		N	+	N	N	N	+	N	N	N	N	+	N	N	N	+
Ossification		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	.	.	1	.	.	.	1	.	.	.	.	.
perivascular; Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	2	1	1	1	1	1	.	1	1	1	1	1	1
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	2	2	1	2	.	3	1	2	1	1	2	1	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	1	2	2	2	2	2	.	2	1	1	1	1	1
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	1	1	1	.	2	1	1	2	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	X	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	.	2	2	2	1	1	2	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	.	2	2	2	2	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	X	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	X
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	X	N	N	N	N	N	N	N	N	N	X	X
PEYERS PATCHES;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	3	2	3	3	3	3	3	3	2	3	3	3	2
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	X	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	+	+	+	+	N	N	+	N	+
Congestion		1	2	1	1	1	1	2	2	1	1	.	.	1	.	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	N	+	+	+	+
Infiltration, Eosinophilic		1	2	2	1	1	1	1	1	2	1	.	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	1	.	.	
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		N	+	+	+	+	+	N	+	N	+	N	N	N	N	+
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	2	1	1	1	1	.	1	.	1	.	.	.	.	2
THYROID, LEFT;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	+	N	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	.	.	1	.	.	.	
UTERUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
VAGINA;		+	N	+	N	N	+	N	N	N	N	N	+	N	N	N
Keratinization; epithelial		2	.	2	.	.	1	.	.	.	.	.	2	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
ADRENAL GLAND, LEFT;		+	N	+	N	N	N	N	N	N	+	N	N	N	N
Dilation; vascular		1	.	1	.	.	.	.	.	.	1	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	+	N	N	N	N	N	N	N	+	N	N	N	N
Dilation; vascular		.	1	.	.	.	.	.	.	.	1	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		+	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		1	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		+	N	N	+	+	+	N	N	N	N	+	N	+	+
Keratinization; epithelial		2	.	.	2	2	2	.	.	.	.	1	.	2	2
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		+	N	N	N	N	+	N	N	N	+	N	N	N
Infiltration, Lymphocytic		1	.	.	.	.	1	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	2	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	+	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	2	.
HEART;		N	N	N	+	N	+	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	1	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	1	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.

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Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)															
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	3	.	3	3	3	3	3	.	.	.	.
Scab; epidermal		.	.	2	.	.	1	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	.	2	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
subcutis; Edema		3	3	3	3	3	3	3	3	3	3	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1
intramuscular / interstitial; Inflammation; mixed		2	2	2	2	2	3	2	2	2	3	.	.	.	.
intramuscular / interstitial; Edema		2	1	1	2	1	1	1	1	1	1	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	1
inter- / perimuscular; Edema		3	3	3	2	3	3	3	3	3	3	.	.	.	.
epidermis; Ulceration		.	.	.	3	3	.	.	3	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	+
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)															
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	1
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation;															
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;															
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;															
mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	2
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	+	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	3	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	N	N	N	N	N	N	+	N	+	+	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	2	.	2	1	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	3	3	2	2	3	2	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	1	.
Mineralization		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	3	3	2	2	2	2	2	3	3	3	2	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	2	3	3	3	2	2	2	2	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	.	1	1	1	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	1	.	1	1
periportal; Vacuolation; hepatocellular		1	2	2	2	2	1	1	2	1	2	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	N	N	N	N	+	N	N	+	+	+	N	+
Ossification		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	2	2	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	1	.	.	.	.	.	.	.	1	.	.	.	1
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	1	1	.	2	1	1	2	2	2	1	2	.
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	1	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	.	1	1	1	1	1	1	1	1	1	1	2	1
Plasmacytosis		.	1	.	.	.	.	2	.	.	1	.	2	1	.	1
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	1	2	2	.	2	2	2	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	1	1	.	.
germinal center; Increased Cellularity		.	.	2	3	2	2	2	2	2	1	2	2	1	2	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		3	1	1	2	2	2	2	2	2	3	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	1	2	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	1	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	+	N	N	N	N	+	N	N	N	N	N	N
Hemorrhage; acute		.	.	2	.	.	.	.	1	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	+	N	N	N	X	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	2	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N
Fibrosis; interstitial		.	.	.	.	.	.	.	.	2	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PEYERS PATCHES;		+	X	X	+	X	+	+	+	+	X	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	.	.	2	.	2	3	3	3	.	3	3	3	3
PITUITARY GLAND;		N	+	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	1	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	+	+	N	+	+	N	N	+
Congestion		1	1	2	2	1	1	2	1	1	.	1	1	.	2
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	N	N	+	+	+	N	+	+	+	+	+	+
Infiltration, Eosinophilic		.	1	.	.	1	1	1	.	1	.	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		1	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	2	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	1	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	+	+	N	+	+	N	+	+	+	N	+	N	N	+
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	1	2	.	2	2	.	1	1	1	.	1	.	.	1
THYROID, LEFT;		N	N	+	N	+	N	N	N	N	+	N	N	N	N	N
Cyst; keratinized		.	.	1	.	1	.	.	.	.	1	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	+	N	N	N	+	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		+	N	N	N	+	+	N	N	N	N	N	N	N	N
Dilation		2	.	.	.	2	2	.	.	.	.	.	.	.	.
VAGINA;		+	N	N	+	+	+	+	N	N	N	N	+	N	+
Keratinization; epithelial		2	.	.	2	2	2	1	.	.	.	.	1	.	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
ADRENAL GLAND, LEFT;		N	N	+	+	N	+	N	N	N	N	N	+	+	+
Dilation; vascular		.	.	1	.	.	1	.	.	.	.	.	1	1	1
Hypertrophy; cortical		.	.	.	2	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	+	N	+	N	N	N	N	N	N	N	N
Dilation; vascular		.	.	.	.	.	1	.	.	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	2	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	1	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	+	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	2	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		N	N	N	+	N	N	N	+	N	+	+	+	N	N
Keratinization; epithelial		.	.	.	2	.	.	.	2	.	2	1	2	.	.
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		+	N	+	N	+	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	1	.	.	.	.	.	.	2	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		2	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	+	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	1	.	1	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
INJECTION SITE I; (Continued)															
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	3	2	2	3	2	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		1	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	.	2	2	2	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
subcutis; Edema		3	.	3	4	4	3	3	3	3	2	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	.	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1
intramuscular / interstitial; Inflammation; mixed		2	3	3	3	2	3	3	3	2	2	.	.	.	.
intramuscular / interstitial; Edema		2	2	1	.	2	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	1	1
inter- / perimuscular; Inflammation; mixed		3	4	3	3	4	4	3	3	3	3	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1
inter- / perimuscular; Edema		3	3	3	3	4	3	3	3	3	1	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
INJECTION SITE II; (Continued)															
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation;															
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;															
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;															
mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	+	N	N	N	N	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	2	.	.	.	.	.	.	.	2
INTESTINE, COLON;		+	N	N	N	N	+	N	N	N	N	N	N	+	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		2	.	.	.	.	2	.	.	.	.	.	.	2	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	1	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	3	3	3	2	2	3	3	3	3
Infiltration, Lymphocytic		.	.	1	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	2	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	1	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	3	2	3	3	3	2	2	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	1	.	.	.	1	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	X	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	2	2	3	2	3	2	2	3	2	2
Hematopoiesis; extramedullary		1	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
LIVER; (Continued)															
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	.	.	1	.	.	.	.	.	1	1	1	1	.
periportal; Vacuolation; hepatocellular		1	2	1	.	.	1	.	1	1	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	N	N	+	+	+	N	+	N	N	N	+	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	.	.	.	.	2	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;															
Hyperplasia		.	.	.	.	1	2	1	.	1	.	.	.	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	1	.	.	.	.	.	1	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	2	1	2	1	2	1	1	2	2	1	2	2
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	3	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	.	.	2	.	.	2	2	1	2	1	1	2	1
Plasmacytosis		2	2	1	2	2	.	.	.	2	2	.	1	.	1
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	1	.	.	2	.	.	.	.	2	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	2	1	2	2	2	2	3	2	2	1	3	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	1	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	2	2	1	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2
MAMMARY GLANDS;		+	N	N	N	+	N	N	+	N	N	N	N	N	N
interstitium; Inflammation; mixed		2	.	.	.	1	.	.	2	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	+	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	N	N	+	N	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	1	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		1	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	+	N	N	N	N	+	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	1	.	.	.	.	1	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	2	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	X	N	N	N	X	X	X	N	X	X	X
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	X	N	N	X	N	X	N	N	X	N	X	N	N
PEYERS PATCHES;		+	X	+	+	N	+	X	+	+	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	2	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	2	.
germinal center; Increased Cellularity		3	.	3	3	.	3	.	3	3	3	2	3	3	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	+	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	1	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		N	N	N	+	+	N	N	+	+	N	+	+	+	N	+
Congestion		.	.	.	.	1	.	.	1	2	.	2	1	1	.	2
Hematopoiesis; increased		.	.	.	1	.	.	.	1	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		N	+	+	+	N	N	+	N	+	N	N	N	+	+	+
Infiltration, Eosinophilic		.	1	1	.	.	.	1	.	1	.	.	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	1	.	.	.	1	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	2	.	.	
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		N	N	N	N	N	+	N	N	N	+	+	N	N	N	N
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	1	.	.	.	1	1	.	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	X
Cyst; keratinized		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	N	N	N	N	N	N	+	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		+	N	N	+	N	N	+	N	N	+	N	+	N
Dilation		2	.	.	2	.	.	2	.	.	2	.	2	.
VAGINA;		N	+	N	+	N	N	+	+	N	+	+	+	N
Keratinization; epithelial		.	1	.	2	.	.	1	2	.	2	1	2	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	+	+	N	N	+	N
Dilation; vascular		.	.	.	.	.	.	.	.	.	1	1	.	.	1	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	1	1
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		+	N	N	N	N	N	N	N	N	+	N	+	+	+	
Keratinization; epithelial		2	.	.	.	.	.	.	.	.	2	.	2	1	2	
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	+	N	N	+	N	N	N	+	N	+	N	N	N
Infiltration, Lymphocytic		.	.	1	.	.	.	.	.	.	2	.	.	.		
Infiltration; lymphohistiocytic		.	.	.	.	.	2	.	.	.	.	.	.	.		
Infiltration; mixed		.	.	.	.	.	.	.	.	2	.	.	.	.		
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.		
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.		
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.		
macrophage; Pigmentation; brown		.	.	.	.	.	2	.	.	.	.	.	.	.		
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.		
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.		
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.		
HEART;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.		
Infiltration; mixed		.	.	.	.	.	1	.	.	.	.	.	.	.		
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.		
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	3	.	.	.	.	.	.		
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.		
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.		
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.		
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.		

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		2	.	3	.	2	2	2	2	2	2	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	1	2	2	2	2	2	2	2	1	.	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	2	3	2	2	3	2	3	3	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	1	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	1	.	2
intramuscular / interstitial; Inflammation; mixed		3	2	2	2	3	3	3	3	2	3	.	.	.	.	.
intramuscular / interstitial; Edema		2	1	2	.	2	2	1	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	1	2
inter- / perimuscular; Inflammation; mixed		3	3	4	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	2	1	2
inter- / perimuscular; Edema		3	3	4	2	3	3	3	3	3	3	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	+	N	N	N	N	N	N	N	+	N	N	N	+	N
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	.	.	.	1	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
INTESTINE, COLON;		N	+	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	.	.	.	1	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	2	.	.	.	.	.	.	.	2	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		+	+	N	+	N	+	N	N	N	+	N	+	N	N	N
Infiltration, Eosinophilic; increased		1	1	.	1	.	1	.	.	.	1	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	N	+	+	
Congestion		3	2	2	3	3	3	3	3	2	3	3	3	.	3	3
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	2	3	3	3	3	3	2	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	2	2	2	3	2	2	3	3	3	3	3
Hematopoiesis; extramedullary		1	.	.	1	.	1	1	1	1	1	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	1	1	1	.	.	.	.	.	.	.	1	1	.	.
periportal; Vacuolation; hepatocellular		1	2	2	2	2	2	2	2	2	1	.	.	.	.	.
LUNGS WITH BRONCHI;		N	+	N	+	+	+	+	+	+	N	+	N	+	N	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	1	.	1	1	.	1	.	1	.	1	.	1
perivascular; Infiltration, Eosinophilic		.	2	.	.	2	1	.	1	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	1	1	1	1	1	1	1	1	1	1	2	.	1
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		1	1	2	.	1	1	1	2	1	1	2	3	2	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	2	.	1	1	1	.	1	.	.	1	2	1	.
Plasmacytosis		2	3	.	3	3	.	3	3	3	3	1	1	.	.	1
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	2	1	.	.	1
germinal center; Increased Cellularity		2	1	.	1	2	.	2	3	2	3	2	2	2	1	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	1	2	2	2	2	2	2	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	N	+	N	+	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		2	2	.	2	.	1	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	X	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	+	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		X	N	N	N	N	N	N	N	N	N	N	N	N	X	N
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	X
PEYERS PATCHES;		+	+	+	X	+	+	+	+	X	+	N	N	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	2	.
germinal center; Increased Cellularity		3	3	3	.	2	3	3	3	.	2	.	.	3	3	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	X	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	N	+	+	+	N	+	+	+	N
Congestion		1	1	2	1	1	1	.	1	1	1	.	1	2	1	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		2	2	1	2	1	2	1	2	1	2	1	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		N	N	N	+	+	+	N	N	N	+	+	N	N	N	+
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	1	1	2	.	.	.	1	1	.	.	.	1
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	+	N	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	1	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		+	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Dilation		2	.	.	2	.	.	.	.	.	.	.	.	.	.	.
VAGINA;		+	N	N	N	N	N	N	N	N	N	+	N	+	+	+
Keratinization; epithelial		2	.	.	.	.	.	.	.	.	.	2	.	2	1	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		+	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	+	N	N	N	N	N	N	+	N	N	N	N	N	N
Dilation; vascular		.	1	.	.	.	.	.	1	.	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	+	N	+	N	+	+	+	+	N	+	N	N	N	N
surrounding tissue; Inflammation; mixed		.	2	.	2	.	3	1	2	1	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		N	N	N	N	N	+	N	N	N	N	N	+	+	+	N
Keratinization; epithelial		.	.	.	.	.	1	.	.	.	.	.	2	2	2	.
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	N	N	N	+
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	2
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	2
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	3	3	2	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		1	1	2	2	2	2	2	2	2	2	.	.	.	.	.
dermis; subcutis; Inflammation;																
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	2	2	3	3	3	3	3	3	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	1	2	2	2	2	2	2	2	2	1	.	.	.	.
intramuscular / interstitial; Inflammation;																
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
intramuscular / interstitial; Inflammation;																
mixed		2	2	2	2	3	2	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		2	1	2	2	2	2	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	1	1	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation;																
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	1	.
inter- / perimuscular; Edema		3	2	2	3	3	3	3	3	4	4	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	N	+	+	
Hyperplasia; epidermal		3	2	3	2	3	3	3	3	3	3	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		1	2	2	1	2	2	2	2	2	2	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		3	3	3	2	3	3	3	3	3	3	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	2	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Edema		3	3	3	3	3	3	3	4	3	3	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	1	.	1	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	3	.	.	1	2
intramuscular / interstitial; Edema		2	2	2	1	2	2	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	.	.	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	.	2
intramuscular / interstitial; Inflammation; mixed		2	2	3	2	3	3	2	2	2	3	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	+	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	1	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	+	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	+	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	1	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	2	3	3	3	2	3	2	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	2	.	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	2	2	3	3	3	2	3	2	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	2	2	3	3	3	2	3	3	3	3	2	3	3
Hematopoiesis; extramedullary		1	.	1	.	.	.	1	.	1	1	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	1	.
periportal; Vacuolation; hepatocellular		2	2	2	1	2	2	2	2	2	2	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	N	N	+	+	+	+	+	N	+	N	N	+
Ossification		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	1	.	.	.	.	.	1	.	.	1	.	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	1	.	2	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	2	2	2	2	2	1	1	1	2	2	1	1	2
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	1	1	.	.	.	.	.	.	.	.	.	.	.	1
germinal center; Increased Cellularity		2	2	1	2	2	2	2	1	2	2	2	2	2	2	2
LYMPH NODE, ILIAC;		X	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		.	2	2	2	2	2	2	2	2	2	2	1	2	2	2
Plasmacytosis		.	2	2	3	3	2	3	2	3	3	2	2	1	1	2
Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	1	2	3	3	2	1	.	2	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	3	1	2	2	1
germinal center; Increased Cellularity		.	3	2	2	2	2	3	2	3	2	2	2	2	3	3

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Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	1	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	1	2	2	.
MAMMARY GLANDS;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		+	+	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		1	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	+	+	+	+	+	N	+	N	N	N	
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		3	3	3	3	3	2	3	2	3	1	.	2	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	X	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	X	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	+	X	N	N	N	X	X	N	N	N	X	N	X
Fibrosis; interstitial		.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	X	N	N	X	X	X	N	X	N	N	X	X
PEYERS PATCHES;		+	X	+	+	+	+	X	+	+	+	+	+	+	X	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
germinal center; Increased Cellularity		2	.	3	3	3	3	.	3	3	3	3	3	3	.	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	+	+	+	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	3	2	2	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	N	+	+	+	+	N	N	+	+	N	N	+	N
Congestion		.	1	.	.	.	1	1	.	.	1	1	.	.	1	.
Hematopoiesis; increased		2	1	.	1	2	2	1	.	.	1	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	1	1	2	2	1	1	2	2	1	1	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	N	N	+	+	+	N	N	+	N	N	N	N	N	N
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	.	.	1	1	1	.	.	1	.	.	.	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	N	+	N	N	X	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		N	N	N	N	N	N	N	N	N	N	N	+	N	N	N
Dilation		.	.	.	.	.	.	.	.	.	.	.	3	.	.	.
VAGINA;		N	N	N	N	N	+	+	N	N	N	N	+	+	+	+
Keratinization; epithelial		.	.	.	.	.	1	1	.	.	.	.	2	2	2	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 6	1 6	1 6	1 6	1 7	1 7	1 7	1 7	1 7	1 7	1 7	1 7	1 8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		N	N	N	N	+	N	N	N	N	N	N	+	N	N	N
Dilation; vascular		.	.	.	.	1	.	.	.	.	.	.	1	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		N	N	N	+	+	N	N	N	N	+	+	+	N	N	N
Keratinization; epithelial		.	.	.	2	2	.	.	.	.	2	2	2	.	.	.
Cyst; keratinized		.	.	.	.	.	.	.	.	.	3	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	+	N	+	+	+	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	2	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	2	.	2	.	.	.	.	.	.	.
Inflammation; purulent		.	2	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	1
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	N	+
Hemorrhage		.	.	.	.	.	.	2	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	3	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)															
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	3	3	3	3	3	3	3	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	2	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	3	.	2	3	3	3	3	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
subcutis; Edema		3	3	4	3	3	4	4	4	4	3	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		3	2	2	3	3	2	3	3	3	3	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	1	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	1	.	1
inter- / perimuscular; Inflammation; mixed		3	3	3	4	4	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	.	.
inter- / perimuscular; Edema		3	3	4	3	2	3	3	3	3	3	.	.	.	.
epidermis; Ulceration		.	3	.	.	.	.	.	3	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)															
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation;															
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;															
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation;															
mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	+	N	N	+	+	N	N	+	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	3	.	.	2	1	.	.	2	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	N	+	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	1	.	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	3	2	2	2	3	2	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	3	2	2	2	3	2	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	2	2	2	2	2	2	3	2	3	3	2	3
Hematopoiesis; extramedullary		1	1	1	1	.	.	1	.	.	1	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)															
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	1	1	1	1	.
periportal; Vacuolation; hepatocellular		1	1	1	2	2	1	2	2	1	1	.	1	.	.	.
LUNGS WITH BRONCHI;		N	N	+	N	N	+	N	+	+	+	N	N	N	N	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	1	.	.	1	.	1	1	1	.	.	.	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	2	2	2	.	1	2	2	.	1	1	1	1	1
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
germinal center; Increased Cellularity		2	3	2	2	1	2	2	2	2	2	2	2	1	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	1	2	1	2	2	2	2	2	1	1	1	2	2
Plasmacytosis		2	.	2	2	2	2	1	.	.	2	.	.	1	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		1	2	2	2	.	3	.	.	1	3	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	.	1	1	1

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		3	2	2	2	2	2	2	2	2	2	2	2	1	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	2	2	2	2	2	2	2	2	2	2	1	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	+	N	N	+	+	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	2	.	.	3	3	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	X	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	X	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	X	N
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		X	X	N	N	N	N	N	N	N	N	N	X	N	N
PEYERS PATCHES;		+	+	X	+	+	X	+	X	+	+	+	+	X	+
Mineralization		.	1	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	.	3	3	.	2	.	1	2	3	3	3	.	3
PITUITARY GLAND;		N	N	N	N	+	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	1	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	X	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	N	+	+	N	N	+	+	+	+	+	+	+
Congestion		1	1	2	.	1	1	.	.	1	1	1	1	1	2	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		N	N	+	N	N	N	N	+	+	+	+	N	+	+	+
Infiltration, Eosinophilic		.	.	1	.	.	.	.	.	1	1	1	.	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	N	+	N	N	+	N	N	+	+	+	N	N	+	N
Cyst		.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	.	.	.	.	1	.	.	1	2	2	.	.	1	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	X	N	N	N	N	N	+	N	N	N	N	N	+	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	.	.	1	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	+	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	1	.
TRACHEA;		N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.
VAGINA;		N	+	N	+	+	N	N	N	N	+	+	+	N	N	N
Keratinization; epithelial		.	1	.	2	2	.	.	.	.	2	2	2	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		+	N	N	N	N	N	N	+	N	N	N	N	+	N
Dilation; vascular		1	.	.	.	.	.	.	1	.	.	.	.	1	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	1
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	N	+	+	+	N	N	N	N
surrounding tissue; Inflammation; mixed		2	2	3	2	3	2	.	2	2	2	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		X	N	N	+	N	N	N	N	N	N	N	+	N	+
Keratinization; epithelial		.	.	.	2	.	.	.	.	.	.	.	1	.	2
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	2	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	+	+	N	N	N	N	+	+	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	2	1	.	.	.	.	1	2	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	N	+	+	
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)															
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	2	3	3	3	3	3	3	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	1	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	1	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	2	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
subcutis; Edema		4	3	3	2	3	3	3	2	3	3	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	.	1	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	.	2	2
intramuscular / interstitial; Inflammation; mixed		2	2	3	2	2	2	2	2	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	.	2	2
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	.	2	2
inter- / perimuscular; Edema		4	4	4	3	#	4	3	3	3	3	.	.	.	.	.
epidermis; Ulceration		2	.	.	.	.	.	1	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	+	N	+	+
Hyperplasia; epidermal		3	3	2	3	3	3	.	2	3	2	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	1	1	2	2	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)															
subcutis; Edema		4	3	3	2	4	3	1	1	3	4	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	2	2	3	3	.	.	.	.	.
inter- / perimuscular; Edema		4	3	3	3	4	4	2	2	3	4	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	.	2	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	.	2	1
intramuscular / interstitial; Edema		2	2	2	2	2	2	1	1	2	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	1	.	1	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	.	2	.
intramuscular / interstitial; Inflammation; mixed		2	2	3	2	2	2	2	2	2	2	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	+	N	N	N	N	N	N	+	N	N	N	N	
Infiltration, Eosinophilic; increased		.	.	1	.	.	.	.	.	.	1	.	.	.	.	
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		+	N	+	+	+	N	N	N	+	+	+	N	N	N	+
Infiltration, Eosinophilic; increased		1	.	1	1	.	.	.	.	1	1	1	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	1	.	.	.	.	.	.	.	.	2
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	3	3	2	2	2	3	2	3	2	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	3	3	2	2	2	3	2	2	2	3	2	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	1	.	.	.	1	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	3	2	2	2	2	2	2	2	3	2	2	3
Hematopoiesis; extramedullary		.	.	1	1	1	1	.	.	.	1	.	.	.	.	.

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)															
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
Infiltration, Lymphocytic		.	1	.	.	.	.	.	1	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		2	1	2	2	2	2	2	2	1	2	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	+	N	+	+	+	+	+	N	+	N	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
bronchial-associated lymphoid tissue;															
Hyperplasia		1	.	.	1	.	1	.	1	.	.	.	.	.	.	1
perivascular; Infiltration, Eosinophilic		1	.	1	1	.	1	1	.	1	.	1	.	.	.	1
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	1	.	.	
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	X	+	+	
Histocytosis		1	.	2	1	2	2	2	2	1	2	1	1	.	2	1
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	.	.	2	2	.	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	X	+	+	
Histocytosis		2	2	2	1	1	1	.	1	2	2	1	1	.	1	2
Plasmacytosis		3	3	2	3	3	2	3	3	3	3	2	2	.	1	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	2	2	2	2	.	.	.	2	1	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	2	2	.	3	2
germinal center; Increased Cellularity		3	3	2	2	3	2	3	2	2	2	3	2	.	2	2

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	3	1	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	.	2	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	+	+	+	+	+	N	N	N	N	+	
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		2	3	4	3	3	2	2	1	3	3	.	.	.	.	1
OPTIC NERVE, LEFT;		N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	+	N	N	X	X	X	X	X	N	N	N	N	N
Fibrosis; interstitial		.	2	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		X	X	N	N	N	X	N	N	N	N	N	X	N	N	N
PEYERS PATCHES;		X	+	+	+	+	+	+	+	+	+	+	N	+	+
Mineralization		.	.	.	.	.	.	.	.	1	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	3	2	2	2	3	2	2	2	3	3	3	.	3	3
PITUITARY GLAND;		N	X	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	X	N	N

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		+	N	+	+	N	+	+	N	N	+	N	N	N	N
dermis; subcutis; Infiltration; mixed		2	.	2	1	.	3	1	.	.	3	.	.	.	.
SPINAL CORD;		+	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		2	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	+	+	+	+	+	N	N	+
Congestion		1	.	1	1	1	.	1	1	1	.	1	1	.	.	1
Hematopoiesis; increased		1	1	.	1	.	2	1	1	1	2	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	N	+	+	+	+	N	N	+
Infiltration, Eosinophilic		1	.	2	1	1	1	1	.	2	1	2	1	.	.	2
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	1	.	.	.	.	.	.	.	.	.	.	.	.	1
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	+	+	N	+	+	+	N	+	+	+	N	N	N	N
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	1	1	.	1	1	1	.	1	1	1	.	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	N	+	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.
URINARY BLADDER;		N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.
UTERUS;		N	N	N	+	N	N	N	N	N	N	N	N	N	N
Dilation		.	.	.	2	.	.	.	.	.	.	.	.	.	.
VAGINA;		N	N	N	+	+	N	N	N	N	+	N	N	+	+	+
Keratinization; epithelial		.	.	.	2	1	.	.	.	.	2	.	.	1	1	2

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

Key Page

Group

Code	Description
1	Group 1: Control
2	Group 2: 30 µg BNT162a1
3	Group 3: 10 µg BNT162a1
4	Group 4: 30 µg BNT162b1
5	Group 5: 100 µg BNT162b1
6	Group 6: 30 µg BNT162c1
7	Group 7: 100 µg BNT162b2

Removal Reason

Code	Description
Term	Killed Terminal

Tissue Result

Code	Description
N	Normal
.	Not Recorded
+	Tissue Observation Present
X	Not Examined

Grade

Code	Description
.	not recorded
1	minimal
2	mild
3	moderate
4	marked
#	duplicate
P	present - no grade or classification

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	1	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : Inflammation; lymphohistiocytic, focal, mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	2	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE II : Inflammation; mixed, focal, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : acinar cell; Hyperplasia; focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	3	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	4	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Vacuolation; hepatocellular, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	5	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration; mixed, multifocal, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LUNGS WITH BRONCHI : macrophage; Pigmentation; brown, focal, minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : Infiltration; lymphohistiocytic, focal, minimal
TRACHEA : macrophage; Pigmentation; brown, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, CERVICAL - Not Present
MAMMARY GLANDS - Not Present
PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	6	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : myofiber; Degeneration; multifocal, minimal
INJECTION SITE I : muscle; Regeneration; multifocal, minimal
INJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Inflammation; purulent, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration, Lymphocytic; multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	7	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LUNGS WITH BRONCHI : Emphysematous (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	8	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : Inflammation; lymphohistiocytic, focal, minimal
INJECTION SITE II : Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
THYROID, LEFT : Cyst; keratinized, single, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal
TONGUE : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, CERVICAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	9	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

THYMUS : Discolouration; reddened (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, mild
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Infiltration, Eosinophilic; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	10	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : Inflammation; lymphohistiocytic, focal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Necrosis; focal, mild
LIVER : Infiltration, Neutrophilic; focal, mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : Cyst; single, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	11	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	12	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : Inflammation, Granulomatous; follicular, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars intermedia; Cyst; minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYROID, LEFT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	13	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	14	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TESTIS, LEFT : Spermatid Giant Cells; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	15	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

TESTIS, RIGHT : Enlarged (TGL) [TESTIS, RIGHT : Dilation; tubular, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TESTIS, LEFT : Dilation; tubular, mild
TESTIS, RIGHT : Dilation; tubular, moderate [TESTIS, RIGHT : Enlarged (G)]
TESTIS, RIGHT : Infiltration; lymphoplasmacytic, focal, moderate
TESTIS, RIGHT : Spermatocoele; single, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	16	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	17	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

INJECTION SITE I : Hemorrhage; focal, mild
INJECTION SITE I : Inflammation; mixed, focal, minimal
INJECTION SITE II : myofiber; Degeneration; focal, minimal
INJECTION SITE II : Inflammation; mixed, multifocal, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, mild
KIDNEY, RIGHT : pelvis; Inflammation; purulent, mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild
TRACHEA : Infiltration; mixed, minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	18	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
ADRENAL GLAND, RIGHT : (Comment) artefacts
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : Inflammation; lymphohistiocytic, focal, minimal
INJECTION SITE I : Foreign Material; hair, focal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : acinar cell; Atrophy; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	19	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TONGUE : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	20	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

INJECTION SITE I : Inflammation; granulomatous, focal, minimal
INJECTION SITE II : muscle; Regeneration; focal, minimal
INJECTION SITE II : Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	21	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EYE, LEFT : macrophage; Pigmentation; brown, focal, mild
HEART : (Comment) artefacts
INJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	22	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
INJECTION SITE II : Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYROID, LEFT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	23	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
SKELETAL MUSCLE : Infiltration, Lymphocytic; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, MESENTERIC - Not Present
SALIVARY GLANDS, SUBLINGUAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	24	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Hemorrhage; acute, mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	25	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, mild
INJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : dermis; subcutis; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	26	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
INTESTINE, RECTUM : Nematodiasis; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, LEFT : tubule; Cast; hyaline, multifocal, mild
KIDNEY, LEFT : tubule; Degeneration; hyaline, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Ossification; focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	27	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	28	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Cyst; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, LEFT - Insufficient Tissue To Evaluate

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	29	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	30	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	31	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, mild
INTESTINE, RECTUM : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	31 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	32	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : inter- / perimuscular; Edema; mild
INJECTION SITE I : Hyperplasia; epidermal, mild
INJECTION SITE II : Hyperplasia; epidermal, focal, moderate
INJECTION SITE II : subcutis; Edema; focal, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; focal, mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; focal, mild
INJECTION SITE II : subcutis; Inflammation; mixed, focal, mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, focal, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	32 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	33	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)

PROSTATE GLAND : Reduced In Size (TGL)

SEMINAL VESICLES : Reduced In Size (TGL)

ADRENAL GLAND, LEFT : Enlarged (TGL)

ADRENAL GLAND, RIGHT : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : myofiber; Degeneration; mild

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	33 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : Hyperplasia; epidermal, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : Ossification; focal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : pars distalis; Cyst; single, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	34	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, focal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, focal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

INJECTION SITE I : subcutis; Inflammation; mixed, focal, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

INJECTION SITE I : Hyperkeratosis; epidermal, focal, moderate

INJECTION SITE I : Hyperplasia; epidermal, focal, moderate

INJECTION SITE II : myofiber; Degeneration; mild

INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate

INJECTION SITE II : subcutis; Edema; moderate

INJECTION SITE II : inter- / perimuscular; Edema; mild

INJECTION SITE II : myofiber; Necrosis; focal, minimal

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild

INJECTION SITE II : subcutis; Inflammation; mixed, moderate

INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, moderate

INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate

KIDNEY, LEFT : Congestion; mild

KIDNEY, RIGHT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	34 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, RIGHT : (Comment) incomplete

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	35	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : (Comment) artefacts
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration; mixed, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	35 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

AORTA ABDOMINALIS - Not Present
PEYERS PATCHES - Not Present
URINARY BLADDER - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	36	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : epidermis; Ulceration; multifocal, mild
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : (Comment) artefacts
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	36 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SALIVARY GLANDS, PAROTIS : Infiltration, Lymphocytic; multifocal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYROID, RIGHT : Cyst; keratinized, multiple, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PROSTATE GLAND - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	37	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]
INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]
INJECTION SITE II : Incrusted (TGL) [INJECTION SITE II : Scab; epidermal, focal, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : dermis; subcutis; Necrosis; multifocal, mild
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : Hyperplasia; epidermal, focal, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : Scab; epidermal, focal, mild [INJECTION SITE II : Incrusted (G)]
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : myofiber; Necrosis; traumatic, focal, minimal
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	37 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	38	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : epidermis; Ulceration; focal, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	39	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : muscle; Regeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, focal, moderate
INJECTION SITE II : Scab; epidermal, focal, mild
INJECTION SITE II : dermis; subcutis; Necrosis; focal, moderate
INJECTION SITE II : Ulceration; epidermal, focal, mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	39 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; marked
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	40	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	40 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	41	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration; lymphohistiocytic, focal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE I : inter- / perimuscular; Mineralization; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Multinucleated Macrophages; multifocal, mild
INTESTINE, COLON : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration, Lymphocytic; multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	41 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	42	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE I : inter- / perimuscular; Mineralization; multifocal, mild
INJECTION SITE I : inter- / perimuscular; Multinucleated Macrophages; multifocal, mild
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : macrophage; alveolus; Infiltration; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SEMINAL VESICLES : Infiltration, Lymphocytic; focal, minimal
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	43	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	44	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : macrophage; Pigmentation; brown, focal, minimal
PITUITARY GLAND : pars distalis; Cyst; few, mild
PROSTATE GLAND : Infiltration, Lymphocytic; focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present
TESTIS, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	45	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : macrophage; Pigmentation; brown, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : (Comment) incomplete
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	46	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	46 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : (Comment) artefacts
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	47	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : (Comment) artefacts
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Inflammation, Chronic; interstitial, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : Hemorrhage; acute, focal, mild
PITUITARY GLAND : pars distalis; Cyst; single, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	47 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	48	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Scab; epidermal, focal, mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, mild
SPLEEN : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	48 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

THYMUS : Hemorrhage; acute, multifocal, mild
THYROID, LEFT : Cyst; keratinized, single, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	49	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : epidermis; Ulceration; focal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : epidermis; Ulceration; focal, moderate [INJECTION SITE I : Incrusted (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	49 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	50	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : epidermis; Ulceration; focal, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	50 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, mild
THYROID, LEFT : Cyst; keratinized, single, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	51	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

UTERUS : Dilation (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration; lymphohistiocytic, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Scab; epidermal, focal, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, LEFT : tubule; Cast; hyaline, multifocal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	51 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : chief cell; Hyperplasia; mild
THYMUS : Hemorrhage; acute, multifocal, mild
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	52	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Mineralization; focal, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	52 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : Mineralization; focal, mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	53	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : epidermis; Ulceration; focal, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : epidermis; Ulceration; focal, moderate [INJECTION SITE I : Incrusted : (Comment) skin (G)]

INJECTION SITE I : myofiber; Degeneration; mild

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	53 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Ossification; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	54	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	54 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PARATHYROID, LEFT : Fibrosis; interstitial, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	55	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, multifocal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	55 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, LEFT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	56	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYROID, RIGHT : Cyst; keratinized, multiple, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	57	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Pyelonephritis; minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	58	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
HARDERIAN GLAND, RIGHT : Inflammation, Chronic; focal, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	59	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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HISTOPATHOLOGY REPORT PAGE: 370

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	60	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : dermis; subcutis; Fibrosis; multifocal, mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : (Comment) artefacts
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	61	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration; lymphohistiocytic, focal, moderate
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : epidermis; Ulceration; multifocal, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Indurated (G)]
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	61 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	62	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; mild
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : Hemorrhage; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration; mixed, focal, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	62 (Continued)	Group:	3 - Group 3	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	63	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : subcutis; Hemorrhage; focal, mild

INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : epidermis; Ulceration; focal, moderate

INJECTION SITE I : myofiber; Degeneration; mild

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	63 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	64	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	64 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	65	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Scab; epidermal, focal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	65 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present
SALIVARY GLANDS, PAROTIS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	66	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; minimal (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	66 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; multifocal, minimal
PEYERS PATCHES : Inflammation, Granulomatous; follicular, multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Cyst; single, mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	67	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	67 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	68	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	69	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; mild
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	70	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Inflammation, Chronic; focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : inter- / perimuscular; Edema; mild
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	70 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

TRACHEA : Infiltration; mixed, minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	71	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, mild
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	72	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : (Comment) artefacts
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; focal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	73	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; moderate
INTESTINE, RECTUM : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; focal, moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	74	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, mild
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : Infiltration; mixed, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TONGUE : Granuloma; hair, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	75	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; moderate
KIDNEY, LEFT : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : tubule; Basophilia; multifocal, moderate
KIDNEY, RIGHT : Inflammation, Chronic; interstitial, multifocal, moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : Hemorrhage; acute, focal, mild
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	76	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Inflammation, Chronic; focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Necrosis; multifocal, minimal
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
NERVE, SCIATIC : perineural; Inflammation; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	76 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; moderate
UTERUS : Dilation; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	77	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; mixed, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	78	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; mixed, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Inflammation, Chronic; interstitial, focal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	78 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	79	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

UTERUS : Dilation (TGL) [UTERUS : Dilation; mild (H)]

UTERUS : Filled With Liquid : (Comment) clear (TGL) [UTERUS : Dilation; mild (H)]

ADRENAL GLAND, LEFT : Enlarged (TGL) [ADRENAL GLAND, LEFT : Hypertrophy; cortical, mild (H)]

ADRENAL GLAND, RIGHT : Enlarged (TGL) [ADRENAL GLAND, RIGHT : Hypertrophy; cortical, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Hypertrophy; cortical, mild [ADRENAL GLAND, LEFT : Enlarged (G)]
ADRENAL GLAND, RIGHT : Hypertrophy; cortical, mild [ADRENAL GLAND, RIGHT : Enlarged (G)]
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Mineralization; focal, mild
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	79 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : Vacuolation; multifocal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
TRACHEA : (Comment) artefacts
UTERUS : Dilation; mild [UTERUS : Filled With Liquid : (Comment) clear (G) | UTERUS : Dilation (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LACRIMAL GLAND, RIGHT - Not Present
PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	80	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, minimal
HEART : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	80 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

MAMMARY GLANDS : interstitium; Inflammation; mixed, multifocal, minimal
SPLEEN : Congestion; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	81	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	81 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : macrophage; Pigmentation; brown, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	82	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

UTERUS : Dilation (TGL)
UTERUS : Filled With Liquid : (Comment) clear (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : Infiltration, Lymphocytic; focal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	82 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Infiltration, Lymphocytic; focal, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	83	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

UTERUS : Dilation (TGL)

UTERUS : Filled With Liquid : (Comment) clear (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	83 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	84	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Enlarged (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : surrounding tissue; muscle; Infiltration; mixed, focal, mild
HARDERIAN GLAND, RIGHT : Infiltration; mixed, multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	84 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	85	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration; mixed, multifocal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; minimal [INJECTION SITE I : Thickened (G)]
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	85 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

OPTIC NERVE, RIGHT : macrophage; Infiltration; foamy, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, LEFT : Cyst; keratinized, single, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	86	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : (Comment) artefacts
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : macrophage; Pigmentation; brown, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : pars intermedia; Cyst; minimal
SPLEEN : Congestion; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	87	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Erythrophagocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	88	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; lymphohistiocytic, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	89	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : Inflammation, Granulomatous; follicular, multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration, Lymphocytic; multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	90	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Cyst; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
THYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	91	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, marked (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Necrosis; focal, mild
LIVER : Infiltration, Neutrophilic; focal, mild
LIVER : Infiltration, Lymphocytic; focal, minimal
LIVER : Vacuolation; hepatocellular, focal, mild
LUNGS WITH BRONCHI : Ossification; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	91 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	92	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
ADRENAL GLAND, RIGHT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : perivascular; Inflammation; plasmacytic, multifocal, moderate
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : tubule; Basophilia; multifocal, minimal
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	92 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Erythrophagocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	93	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, RECTUM : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Infiltration, Eosinophilic; focal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	93 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

MAMMARY GLANDS - Not Present
OPTIC NERVE, RIGHT - Not Present
PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present
THYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	94	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; mild
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Inflammation; purulent, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	94 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	95	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration; mixed, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	95 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present
URINARY BLADDER - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	96	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	96 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	97	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration; mixed, multifocal, minimal
INJECTION SITE I : subcutis; Inflammation; mixed, mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	97 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	98	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]
SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Mineralization; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	98 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration; mixed, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Infiltration, Lymphocytic; focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	99	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, marked (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LUNGS WITH BRONCHI : Infiltration; lymphohistiocytic, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	99 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	100	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HEART : Infiltration; lymphohistiocytic, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, mild
KIDNEY, LEFT : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	100 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, focal, mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	101	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
TRACHEA : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	102	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Vacuolation; hepatocellular, multifocal, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; widespread, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	103	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

TESTIS, RIGHT : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Oligospermia; mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LIVER : Necrosis; focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
SPLEEN : Congestion; minimal
TESTIS, LEFT : Dilation; tubular, mild
TESTIS, RIGHT : Dilation; tubular, moderate
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	103 (Continued)	Group:	4 - Group 4	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	104	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : macrophage; alveolus; Infiltration; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	105	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, RECTUM : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : macrophage; Infiltration; foamy, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; focal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	106	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration; mixed, focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	106 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	107	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : subcutis; Edema; mild
INJECTION SITE I : intramuscular / interstitial; Edema; minimal
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	107 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	108	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	108 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	109	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H)]
UTERUS : Dilation (TGL) [UTERUS : Dilation; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; mild
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
OPTIC NERVE, RIGHT : macrophage; Pigmentation; brown, focal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
UTERUS : Dilation; mild [UTERUS : Dilation (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	109 (Continued)	Group:	4 - Group 4	Sex:	Female

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	110	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	110 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	111	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, mild
HARDERIAN GLAND, LEFT : macrophage; Pigmentation; brown, focal, mild
HEART : (Comment) artefacts
HEART : Infiltration; mixed, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
NERVE, SCIATIC : perineural; Inflammation; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	111 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

PANCREAS : acinar cell; Atrophy; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	112	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hemorrhage; focal, moderate
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Cyst; tubular, single, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	112 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	113	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	114	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : (Comment) artefacts

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	114 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TONGUE : Hemorrhage; acute, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	115	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; mixed, multifocal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	115 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

SALIVARY GLANDS, SUBLINGUAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	116	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : Infiltration, Lymphocytic; focal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	117	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : (Comment) artefacts
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	118	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	119	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : (Comment) artefacts
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Inflammation, Granulomatous; follicular, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	120	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	121	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Enlarged (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)
SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]
INJECTION SITE II : Enlarged (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked [INJECTION SITE II : Enlarged (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	121 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : subcapsular; Infiltration, Neutrophilic; focal, minimal
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LIVER : kupffer cell; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
LYMPH NODE, RENAL : Histocytosis; mild
LYMPH NODE, RENAL : macrophage; Pigmentation; brown, focal, minimal
LYMPH NODE, RENAL : germinal center; Increased Cellularity; minimal
NERVE, SCIATIC : perineural; Inflammation; minimal
PANCREAS : Infiltration, Lymphocytic; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	122	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; mild
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : tubule; Cast; hyaline, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	122 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Infiltration, Eosinophilic; minimal
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : (Comment) artefacts
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SEMINAL VESICLES : surrounding tissue; fat; Infiltration; mixed, focal, moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	123	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, minimal (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H)]
LYMPH NODE, ILIAC : Enlarged (TGL)
SPLEEN : Enlarged (TGL)
INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphocytic, focal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, minimal [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INTESTINE, RECTUM : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	123 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node, subcutis, dermis
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	124	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)
INJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	124 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; marked
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : Infiltration, Eosinophilic; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	125	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	125 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Inflammation; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	126	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	126 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Inflammation, Chronic; interstitial, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	127	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

ADRENAL GLAND, LEFT : Enlarged (TGL)

ADRENAL GLAND, RIGHT : Enlarged (TGL)

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

EYE, RIGHT : (Comment) artefacts

INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : subcutis; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : myofiber; Degeneration; mild

INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	127 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; focal, minimal
SKIN : subcutaneous; Infiltration; mixed, focal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	128	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : surrounding tissue; muscle; Infiltration; mixed, multifocal, mild
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	128 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	129	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : Inflammation; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) artefacts
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	129 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PROSTATE GLAND - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	130	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, minimal (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL)

ADRENAL GLAND, LEFT : Enlarged (TGL)

ADRENAL GLAND, RIGHT : Enlarged (TGL)

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, minimal [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	130 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	131	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	132	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; minimal (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
INTESTINE, RECTUM : (Comment) artefacts
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	132 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	133	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	133 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

PROSTATE GLAND : Inflammation; purulent, focal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	134	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : intramuscular / interstitial; Fibrosis; minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

SALIVARY GLANDS, PAROTIS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	135	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; moderate (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BRAIN, CEREBELLUM : (Comment) artefacts
BRAIN, CEREBRUM : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	135 (Continued)	Group:	5 - Group 5	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	136	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Necrosis; focal, mild
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; minimal
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	136 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; focal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, ILIAC - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	137	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; minimal
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	137 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration, Eosinophilic; minimal
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Infiltration, Eosinophilic; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; lymphohistiocytic, focal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	138	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

INJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	138 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]

INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PARATHYROID, LEFT : Fibrosis; interstitial, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	138 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	139	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : Inflammation; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

INJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE II : subcutis; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EYE, LEFT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; minimal
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; minimal [INJECTION SITE II : Thickened (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	139 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	140	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H) | LYMPH NODE, ILIAC : Inflammation; moderate (H)]

INJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : surrounding tissue; muscle; Infiltration; mixed, focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	140 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; moderate [SPLEEN : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	141	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]
SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, minimal
EYE, LEFT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	141 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

URINARY BLADDER - Insufficient Tissue To Evaluate

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	142	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

NERVE, SCIATIC : (Comment) left

NERVE, SCIATIC : Adhesion : (Comment) to injection site I (TGL) [NERVE, SCIATIC : perineural; Inflammation; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

INJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	142 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Ossification; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate [NERVE, SCIATIC : Adhesion : (Comment) to injection site I (G)]
SKIN : dermis; subcutis; Infiltration; mixed, mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYROID, LEFT : Cyst; keratinized, single, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	143	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; moderate
INJECTION SITE II : inter- / perimuscular; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	143 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, mild
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, focal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	144	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; marked
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	144 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OVIDUCT, LEFT - Not Present
PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	145	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; marked
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : macrophage; alveolus; Infiltration; foamy, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	145 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	146	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Infiltration; lymphohistiocytic, focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	147	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

UTERUS : Dilation (TGL) [UTERUS : Dilation; moderate (H)]
UTERUS : Filled With Liquid : (Comment) clear (TGL) [UTERUS : Dilation; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; multifocal, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : Inflammation, Granulomatous; follicular, multifocal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
UTERUS : Dilation; moderate [UTERUS : Dilation (G) | UTERUS : Filled With Liquid : (Comment) clear (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	148	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Mineralization; focal, minimal
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	149	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; minimal (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OVIDUCT, RIGHT - Not Present
PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	150	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : macrophage; Pigmentation; brown, focal, mild
HARDERIAN GLAND, LEFT : Inflammation, Chronic; focal, mild
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Infiltration; mixed, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	151	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Necrosis; focal, minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	151 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa; Infiltration, Neutrophilic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	152	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : myofiber; Necrosis; focal, minimal
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	152 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, focal, minimal
LIVER : Infiltration; mixed, focal, minimal
LIVER : Necrosis; focal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; focal, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

BONE, STERNUM - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	153	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	153 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Inflammation; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	154	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; moderate
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, mild
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration; mixed, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	154 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	155	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL)
SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LUNGS WITH BRONCHI : Infiltration; lymphohistiocytic, focal, mild
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	156	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Inflammation; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : myofiber; Degeneration; mild

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	156 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Inflammation; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Inflammation; purulent, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	157	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	157 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	158	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : Scab; epidermal, multifocal, mild (H) | INJECTION SITE I : epidermis; Ulceration; multifocal, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : epidermis; Ulceration; multifocal, mild [INJECTION SITE I : Incrusted (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	158 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Scab; epidermal, multifocal, mild [INJECTION SITE I : Incrusted (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	159	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, mild
KIDNEY, RIGHT : tubule; Dilation; focal, mild
LIVER : Congestion; moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	159 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; lymphatic; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	160	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Infiltration; lymphohistiocytic, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	160 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	161	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration; mixed, multifocal, minimal
LIVER : Necrosis; focal, marked
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PITUITARY GLAND : (Comment) incomplete
PROSTATE GLAND : Inflammation; purulent, focal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	162	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	163	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	164	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	165	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	166	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	166 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	167	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Inflammation; purulent, focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : epidermis; Ulceration; multifocal, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	167 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
THYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	168	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	168 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Cyst; focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	169	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BRAIN, CEREBRUM : (Comment) artefacts
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Inflammation; granulomatous, focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]

INJECTION SITE I : myofiber; Degeneration; moderate
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	169 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYROID, RIGHT : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	170	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	170 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars distalis; Cyst; few, minimal
SPLEEN : Congestion; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	171	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Inflammation; granulomatous, focal, mild
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	171 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present
SALIVARY GLANDS, PAROTIS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	172	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : myofiber; Degeneration; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : myofiber; Degeneration; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EYE, LEFT : (Comment) artefacts
EYE, RIGHT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hemorrhage; focal, mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	172 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : Hemorrhage; acute, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
TRACHEA : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OVARY, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	173	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : epidermis; Ulceration; focal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Inflammation; vascular, multifocal, moderate
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : epidermis; Ulceration; focal, moderate [INJECTION SITE I : Incrusted (G)]
INJECTION SITE I : myofiber; Degeneration; moderate
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	173 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : chief cell; Hyperplasia; multifocal, mild
THYROID, RIGHT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	174	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; moderate
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Scab; epidermal, focal, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	174 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	175	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
EYE, RIGHT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : myofiber; Degeneration; moderate
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
KIDNEY, LEFT : Congestion; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	175 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Erythrophagocytosis; minimal
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
THYMUS : Hemorrhage; acute, multifocal, mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	176	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
CERVIX : Cyst; keratinized, moderate
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

NERVE, SCIATIC - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	177	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	178	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, focal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	179	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration; mixed, focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal
TONGUE : Granuloma; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	180	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	181	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, marked (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]
INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : subcutis; Fibrosis; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	181 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	182	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	182 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, LEFT : tubule; Cast; hyaline, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	183	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Cast; hyaline, multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	183 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars distalis; Cyst; few, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PANCREAS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	184	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

INJECTION SITE I : Enlarged (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]
LYMPH NODE, RENAL : Enlarged (TGL) [LYMPH NODE, RENAL : Plasmacytosis; mild (H) | LYMPH NODE, RENAL : germinal center; Increased Cellularity; mild (H)]
INJECTION SITE II : Enlarged (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : Hemorrhage; focal, mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]

INJECTION SITE I : myofiber; Degeneration; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	184 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Enlarged (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
LYMPH NODE, RENAL : Histocytosis; minimal
LYMPH NODE, RENAL : Plasmacytosis; mild [LYMPH NODE, RENAL : Enlarged (G)]
LYMPH NODE, RENAL : germinal center; Increased Cellularity; mild [LYMPH NODE, RENAL : Enlarged (G)]
NERVE, SCIATIC : perineural; Inflammation; marked
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	185	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; focal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	185 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : pars distalis; Cyst; few, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; mild
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	186	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Necrosis; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	186 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : Plasmacytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars distalis; Cyst; few, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present
PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	187	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL)

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) incomplete
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	187 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration; mixed, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	188	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

INJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Vacuolation; cortical, mild
ADRENAL GLAND, RIGHT : (Comment) artefacts
ADRENAL GLAND, RIGHT : Vacuolation; cortical, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	188 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Thickened (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; multifocal, minimal
KIDNEY, LEFT : Inflammation, Chronic; interstitial, focal, mild
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Mineralization; focal, minimal
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; focal, minimal
NERVE, SCIATIC : perineural; Inflammation; marked
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	189	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Inflammation; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	189 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : Hemorrhage; focal, mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, LEFT : Mineralization; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : Mineralization; multifocal, minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : Necrosis; muscular, multifocal, minimal
SKIN : Infiltration, Neutrophilic; muscular, multifocal, mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : (Comment) artefacts
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	190	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : subcutis; Edema; minimal
INJECTION SITE II : intramuscular / interstitial; Edema; minimal
INJECTION SITE II : inter- / perimuscular; Edema; mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	190 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	191	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) artefacts
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : (Comment) artefacts
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	191 (Continued)	Group:	7 - Group 7	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	192	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HEART : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : (Comment) artefacts
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	193	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	194	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BRAIN, CEREBELLUM : (Comment) artefacts
BRAIN, CEREBRUM : (Comment) artefacts
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	195	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PROSTATE GLAND : Infiltration, Lymphocytic; focal, moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	196	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : epidermis; Ulceration; focal, mild
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	196 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
SKIN : dermis; subcutis; Infiltration; mixed, mild
SPINAL CORD : Cyst; keratinized, single, mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
UTERUS : (Comment) incomplete
VAGINA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

CERVIX - Not Present
PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	197	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

INJECTION SITE I : Adhesion : (Comment) to sciatic nerve and bone, muscle jellied (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Adhesion : (Comment) to sciatic nerve and bone, muscle jellied (G)]

INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : myofiber; Degeneration; mild

INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G)]

INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

INJECTION SITE II : myofiber; Degeneration; mild

INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate

INJECTION SITE II : subcutis; Edema; moderate

INJECTION SITE II : intramuscular / interstitial; Edema; mild

INJECTION SITE II : inter- / perimuscular; Edema; moderate

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild

INJECTION SITE II : subcutis; Inflammation; mixed, moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	197 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : Mineralization; focal, minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PARATHYROID, LEFT : Fibrosis; interstitial, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PITUITARY GLAND - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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HISTOPATHOLOGY REPORT PAGE: 601

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	198	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; moderate
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, CECUM : Infiltration, Eosinophilic; increased, minimal
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	198 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; marked
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : dermis; subcutis; Infiltration; mixed, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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HISTOPATHOLOGY REPORT PAGE: 603

LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	199	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

UTERUS : Dilation (TGL) [UTERUS : Dilation; mild (H)]

UTERUS : Filled With Liquid : (Comment) clear (TGL) [UTERUS : Dilation; mild (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	199 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : subcutis; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : dermis; subcutis; Infiltration; mixed, focal, minimal
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
UTERUS : Dilation; mild [UTERUS : Dilation (G) | UTERUS : Filled With Liquid : (Comment) clear (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	200	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; marked
INJECTION SITE II : myofiber; Necrosis; multifocal, minimal
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	200 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	201	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H)]

NERVE, SCIATIC : (Comment) left

NERVE, SCIATIC : Adhesion : (Comment) to injection site I (TGL)

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : dermis; epidermis; Inflammation; neutrophilic, focal, mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Pustule; epidermal, focal, minimal
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	201 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; mild
KIDNEY, LEFT : Mineralization; multifocal, minimal
KIDNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : Mineralization; multifocal, minimal
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, focal, moderate
SPLEEN : Hematopoiesis; increased, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	202	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE II : subcutis; Edema; minimal (H) | INJECTION SITE II : inter- / perimuscular; Edema; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : epidermis; Ulceration; focal, minimal
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE I : Scab; epidermal, focal, minimal
INJECTION SITE II : myofiber; Degeneration; minimal
INJECTION SITE II : subcutis; Edema; minimal [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; minimal [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	202 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : dermis; subcutis; Infiltration; mixed, minimal
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	203	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : subcutis; Inflammation; mixed, moderate
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; mild
INJECTION SITE I : intramuscular / interstitial; Edema; mild
INJECTION SITE I : inter- / perimuscular; Edema; moderate
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; minimal
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; minimal
INJECTION SITE II : intramuscular / interstitial; Edema; minimal
INJECTION SITE II : inter- / perimuscular; Edema; mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : subcutis; Inflammation; mixed, mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	203 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; moderate
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	204	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

INJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated (G)]

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	204 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	205	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

INJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

NERVE, SCIATIC : (Comment) left

NERVE, SCIATIC : Adhesion : (Comment) to injection site I (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, multifocal, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : myofiber; Degeneration; mild
INJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : intramuscular / interstitial; Edema; mild [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : inter- / perimuscular; Edema; moderate [INJECTION SITE I : Indurated (G)]
INJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
INJECTION SITE II : myofiber; Degeneration; mild
INJECTION SITE II : Hyperplasia; epidermal, widespread, mild
INJECTION SITE II : subcutis; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Edema; mild
INJECTION SITE II : inter- / perimuscular; Edema; marked
INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	205 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

INJECTION SITE II : subcutis; Inflammation; mixed, moderate
INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Infiltration; mixed, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Inflammation; minimal
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, focal, moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	206	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, mild
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INTESTINE, COLON : Infiltration, Eosinophilic; increased, minimal
INTESTINE, RECTUM : Infiltration, Eosinophilic; increased, minimal
KIDNEY, LEFT : Congestion; mild
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	206 (Continued)	Group:	7 - Group 7	Sex:	Female

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	207	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; minimal (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	208	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, minimal
KIDNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Cast; hyaline, focal, minimal
KIDNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Infiltration; mixed, multifocal, mild
LUNGS WITH BRONCHI : macrophage; Pigmentation; brown, multifocal, minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : macrophage; Pigmentation; mild
TRACHEA : Infiltration, Lymphocytic; focal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, CERVICAL - Not Present
LYMPH NODE, ILIAC - Not Present
SALIVARY GLANDS, SUBLINGUAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	209	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; minimal (H) | LYMPH NODE, ILIAC : Plasmacytosis; minimal (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE II : inter- / perimuscular; Fibrosis; mild
INJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : (Comment) incomplete
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	210	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	s 22		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
INJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
INJECTION SITE I : inter- / perimuscular; Fibrosis; mild
INJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
INJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
INJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
INJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
INTESTINE, RECTUM : (Comment) artefacts
INTESTINE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
SKELETAL MUSCLE : Infiltration, Lymphocytic; focal, minimal
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	210 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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LPT Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Key Page

Codes

(TGL) = Trackable Gross Lesion, (MPF) = Major Pathological Finding, (?) = Questionable, (E) = Excluded,
(C) = Clinical Observation, (M) = Mass, (G) = Gross Pathology, (H) = Histopathology

Report Request Items

Animals Included:	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210
Groups:	All
Observation Type:	Gross and Histo
Tissues:	All
Removal Reasons:	All

Group Information

Short Name	Long Name	Type
1	Group 1	Control
2	Group 2	Dose
3	Group 3	Dose
4	Group 4	Dose
5	Group 5	Dose
6	Group 6	Dose
7	Group 7	Dose

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7. APPENDICES

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APPENDIX 1

Certificate of Analysis

POLYMUN SCIENTIFIC
Immunbiologische Forschung GmbH

Donaustraße 99
A-3400 Klosterneuburg, Austria
Tel.: +43-2243-25060-300
Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBL063.3 LNP
Lot: CoVVAC/090320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 26.03.2020

Date: 26.03.20

s 22

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Immunbiologische Forschung GmbH

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Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBL063.1 LNP
Lot: CoVVAC/110320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 26.03.2020

Date: 26.03.2020

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http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBP020.3 LNP
Lot: CoVVAC/100320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 26.03.2020 s 22

Date: 26.03.2020

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http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBP020.1LNP
Lot: CoVVAC/160320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 26.03.2020

Date: 26.03.2020

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POLYMUN SCIENTIFIC
Immunbiologische Forschung GmbH

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Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 2

Product: **CoVVAC**
Batch: RBS004.3 LNP
Lot: CoVVAC/130320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 26.03.2020 s 22

Date: 26.03.2020

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APPENDIX 2

Composition of the Diet; Limitation for Contaminants in the Diet, Drinking Water and Bedding Material

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ABBREVIATIONS

%	per cent
Bq	becquerel
IU	international unit
kg	kilogram
L	litre
mg	milligram
MJ	megajoule
ppb	parts per billion
µg	microgram

Composition of the diet

Standard Diet for Rats and Mice
ssniff® V1534 R/M-H, maintenance diet, pellets 10 mm
ssniff® V1535 R/M-H, maintenance diet, pellets 15 mm

(ssniff Spezialdiäten GmbH, 59494 Soest, Germany)

Ingredients
(average content in the diet %)

Crude protein	19.0
Crude fat	3.3
Crude fibres	5.0
Crude ash	6.4
N-free extracts	54.6
Starch	35.9
Sugar	5.4

Metabolizable Energy (MJ/kg)

Gross energy	16.2
Metabolizable energy	13.5

Amino Acids
(average content in the diet %)

Lysine	1.00
Methionine	0.33
Cystine	0.35
Met + Cys	0.68
Threonine	0.71
Tryptophan	0.25
Arginine	1.19
Histidine	0.48
Valine	0.90
Isoleucine	0.79
Leucine	1.39
Phenylalanine	0.88
Phe + Tyr	1.49
Glycine	0.88
Glutamic acid	4.10
Aspartic acid	1.79
Proline	1.29
Serine	0.99
Alanine	0.82

Minerals
(average content in the diet %)

Calcium	1.00
Phosphorus	0.70
Sodium	0.24
Magnesium	0.22
Potassium	0.92

Trace Elements
(average content diet in mg per 1000 g)

Iron	189
Manganese	68
Zinc	91
Copper	15
Iodine	2.1
Selenium	0.3

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Vitamins (additive per 1 000 g of diet)	
Vitamin A	15000 IU
Vitamin D3	1100 IU
Vitamin E	110 mg
Vitamin K (as MNB)	7 mg
Thiamine (B1)	18 mg
Riboflavin (B2)	22 mg
Pyridoxine (B 6)	21 mg
Cobalamin (B12)	100 µg
Nicotinic acid	115 mg
Pantothenic acid	40 mg
Folic acid	7 mg
Biotin	510 µg
Choline	1370 mg

Fatty Acids	[%]
C 12:0	-
C 14:0	0.01
C 16:0	0.45
C 18:0	0.09
C 20:0	0.01
C 16:1	0.01
C 18:1	0.62
C 18:2	1.76
C 18:3	0.23

Limitation for contaminants in the diet (ppb)

	min.	max.
Aflatoxin (B_1, B_2, G_1, G_2), total		5
Lindane		10
Heptachlor		10
Malathion		1000
DDT (Total)		50
Dieldrin		10
Cadmium		400
Arsenic		1000
Lead		1500
Mercury		100
Selenium	100	600
PCB		50

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Limitation for contaminants in the drinking water [mg/L]

		max.
Iron		0.200
Manganese		0.050
Ammonium		0.50
Chloride		250
Arsenic		0.010
Lead		0.010
Cadmium		0.0030
Chromium		0.050
Cyanide		0.050
Fluoride		1.5
Nickel		0.020
Nitrite		0.50
Nitrate		50
Mercury		0.0010
Vinylchloride		0.00050
Acrylamide		0.00010
Benzene		0.0010
Boron		1.0
Bromate		0.010
Selenium		0.010
Antimony		0.0050
Copper		2.0
Aluminium		0.200
Sodium		200
Sulphate		250
Uranium		0.010
Polycyclic aromatic hydrocarbons		
- Benzo-(b)-fluoroanthene		
- Benzo-(k)-fluoroanthene		
- Benzo-(ghi)-perylene		
- Indeno-(1,2,3-cd)-pyrene	total	0.00010
- Benzo-(a)-pyrene		0.000010
Chlorinated organic compounds		
Trihalogenemethane including Trichloromethane, Bromodichloromethane, Dibromochloromethane and Tribromomethane	total	0.050
- 1,2-Dichloroethane		0.0030
- Tetrachloroethene and Trichloroethene		0.010
- Epichlorohydrine		0.00010
Organic chemical compounds used as pesticides and biocides including their toxic metabolites except for		maximum of 0.00010/substance
- Aldrin		0.000030
- Dieldrin		0.000030
- Heptachlor		0.000030
- Heptachloroepoxide		0.000030
	maximum total of	0.00050
Tritium [Bq/L]		100
pH		between 6.5 and 9.5

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Limitation for contaminants in the bedding material [mg/kg]

	max.
Aflatoxin (B_1)	0.01
Chlordane	0.02
Endrine	0.01
Fluorine	150.00
Lindane	0.10
Heptachlor and epoxide	0.01
DDT, DDE, DDD	0.05
Dieldrin and aldrin	0.01
Arsenic	1.00
Lead	2.50
Mercury	0.10
Nitrite (Na-Nitrite)	15.00
HCB	0.01

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APPENDIX 3

GLP Certificate of the Test Facility LPT

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FREIE UND HANSESTADT HAMBURG
Behörde für Gesundheit und Verbraucherschutz

Gute Laborpraxis / Good Laboratory Practice

GLP – Bescheinigung / Statement of GLP Compliance
(gemäß/according to § 19b (1) Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 2004/9/ EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikaliengesetz and Directive 2004/9/ EEC at:

[x] Prüfeinrichtung/ Test facility [ ] Prüfstandort/ Test site

LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG
Redderweg 8
21147 Hamburg
(Unverwechselbare Bezeichnung und Adresse/Unequivocal name and address)

Prüfungen nach Kategorien/ Areas of Expertise
(gemäß/according ChemVwV-GLP Nr. 5.3/OECD guidance)

Kategorie 2, 3, 4 und 9 (Sicherheitspharmakologie und Auftragsarchiv)

Datum der Inspektion (Abschluss)
Datum der Inspektion/ Date of Inspection:

07. Juli 2016

Die/Der genannte Prüfeinrichtung /Prüfstandort befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.
Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung/ diesem Prüfstandort die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.

The above mentioned test facility/test site is included in the national GLP Compliance Programme and is inspected on a regular basis.

Based on the inspection report it can be confirmed, that this test facility/ test site is able to conduct the aforementioned studies in compliance with the Principles of GLP

Hamburg, den 8. Mai 2017

Amt für Arbeitsschutz - Arbeitsmedizin 1 Hamburg

Behörde für Gesundheit und Verbraucherschutz
Marckmannstraße 129b, 20539 Hamburg

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APPENDIX 4

Analytical report:

'Immunogenicity Assessment of BNT162a1, BNT162b1, BNT162b2 and BNT162c1 in Rat Serum after Repeated Intramuscular Administration'

(No. R-20-0104, provided by BioNtech SE, Germany)

BioNTech SE
An der Goldgrube 12
55131 Mainz, Germany
Phone: +49 (0)6131 9084-0
Telefax: +49 (0)6131 9084-390

R&D STUDY REPORT No. R-20-0104

IMMUNOGENICITY ASSESSMENT OF BNT162a1, BNT162b1, BNT162b2 AND BNT162c1 IN RAT SERUM AFTER REPEATED INTRAMUSCULAR ADMINISTRATION

Version 01
Date: 25JUN2020

Reported by s 22

Test item: serum of rats administered with BNT162a1, BNT162b1, BNT162b2, and BNT162c1
Key words: Coronavirus, COVID-19, ATM material, rat, immunogenicity

This R&D report consists of 33 pages.

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LIST OF ABBREVIATIONS

ATM	Animal trial material
COVID-19	Coronavirus disease 2019
ELISA	Enzyme-linked immunosorbent assay
HR	Heptad repeats
LNP	Lipid nanoparticle
LPT	Laboratory of Pharmacology and Toxicology GmbH, CRO conducting Study 38166
modRNA	Nucleoside-modified mRNA
nAb	Neutralizing antibody
No	Number
PBS	Phosphate-buffered saline
pVNT	Pseudovirus-based neutralization test
RBD	Receptor binding domain
RNA	Ribonucleic acid
S protein	Spike protein
S1	Subdomain 1 of the S protein
S2	Subdomain 2 of the S protein
saRNA	Self-amplifying mRNA
SARS	Severe acute respiratory syndrome
SARS-CoV-2	Severe acute respiratory syndrome-Coronavirus-2
uRNA	Uridine-containing mRNA

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RESPONSIBILITIES

Person responsible for the study:	s 22	23 Jun 2020 Date
Author:	s 22	18 Jun 2020 Date
Reviewer:	s 22	19 JUN 2020 Date
QA representative:	s 22	25.06.2020 Date

Meaning of the signatures:

Person responsible for the study: I am responsible for the content of the R&D report and confirm that it represents an accurate record of the results. This study was performed according to the SOPs and methods as well as the rules and regulations described in the report.

Author: I am the author of this document.

Reviewer: I reviewed the R&D report and confirm that this document complies with the scientific and technical standards and requirements.

QA representative: I confirm that this document complies with the relevant quality assurance requirements.

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1 SUMMARY

BioNTech is developing RNA-based vaccines designed to protect against the novel coronavirus disease that emerged in 2019 (COVID-19). The project involves testing three RNA platforms which are under development at BioNTech with domains of the surface or spike protein (S protein) of the novel Coronavirus (SARS-CoV-2) as the viral antigen.

In the present accessory study to the GLP-compliant repeat-dose toxicity study in rats (LPT Study No. 38166), the immunogenicity of the administered SARS-CoV-2-S protein targeted RNA vaccines BNT162a1, BNT162b1, BNT162b2, and BNT162c1 was investigated. Serum samples were collected from (i) the treated main study animals at day 10 (BNT162c1) or at day 17 after first immunization (BNT162a1, BNT162b1, and BNT162b2) as well as (ii) the treated recovery cohorts at day 31 (BNT162c1) or at day 38 (BNT162a1, BNT162b1, and BNT162b2). The elicited antibody immune responses were analyzed by S1 domain and RBD sub-domain specific ELISA as well as VSV/SARS-CoV-2-S-based pseudovirus neutralization assay (pVNT).

The recorded data demonstrates that all BNT162 vaccine candidates elicited a SARS-CoV-2-S protein specific antibody response directed against the S1 domain and the RBD sub-domain. The antibody response induced by the BNT162c1 vaccine was low in extent and did not confer neutralization activity in most animals. The development of the BNT162c1 candidate was discontinued. For BNT162a1, BNT162b1 and BNT162b2 vaccines, antibody responses detected via ELISA increased over time and directly translated into neutralizing activity as seen in the VSV/SARS-CoV-2-S pseudovirus neutralization test. For those vaccine candidates, sera from animals with higher antigen-specific antibody titers also displayed more pronounced virus neutralization effect and, in case of modRNA based vaccines, BNT162b1 and BNT162b2, exceeded the upper limit of quantification of the assay.

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25 Jun 2020
Date

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2 GENERAL INFORMATION

2.1 Sponsor and Test Facilities

Sponsor

BioNTech RNA Pharmaceuticals GmbH
An der Goldgrube 12
55131 Mainz
Germany

Test Facility

BioNTech SE
An der Goldgrube 12
55131 Mainz
Germany

2.2 Participating Personnel

Responsible person: (as defined in SOP-100-024)
Author:
Experimenter:
Experimenter:
Experimenter:

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2.3 Study Dates

Start of experiments: 07 APR 2020

Completion of experiments: 07 MAY 2020

2.4 Guidelines and Regulations

All experiments are executed in accordance with the existing standard operating procedures and described processes from BioNTech SE. Applicable documents are listed below.

- SOP-010-045 Brutschrank HERAcell 150i
- SOP-010-047 Zentrifuge Eppendorf 5810/5810R
- SOP-010-051 Tiefkühlschränke -80 °C
- SOP-010-058 Sicherheitswerkbank Klasse II
- SOP-010-086 Zentrifuge Thermo Scientific Heraeus Pico und Fresco 17
- SOP-020-009 Ansetzen von Medien und Zusätzen für die Zellkultur
- SOP-030-041 Auftauen von Zellen
- SOP-030-112 Durchführung eines virusprotein-spezifischen ELISA
- SOP-090-013 Biological safety in laboratories
- SOP-110-022 Entsorgung von Biostoffabfällen

2.5 Changes and Deviations

Not applicable. There is no formal R&D plan available.

2.6 Documentation and Archive

Study plans and reports are stored and archived according to SOP-100-003 Archiving of Paper-Based Documents.

Raw data and evaluated data are saved at:

- P:\BioNTechRNA\RN9391R00_CoV-VAC\04_Preclinic\02_Toxicology\Repeat-dose Toxicity\LPT Studie 38166

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3 INTRODUCTION

3.1 Background

In December 2019, an outbreak of pneumonia of unknown cause in Wuhan, Hubei province in China started. The disease spread rapidly and in January 2020, the agent was identified. By June 9th 2020, infection with the novel Coronavirus (SARS-CoV-2) was confirmed in approximately 7,000,000 people with more than 400,000 casualties[1]. A vaccine is urgently needed and BioNTech decided to develop a rapid vaccine project based on the surface or spike protein (S protein) of the virus as the viral antigen. The S protein is a trimer and during viral egress, the precursor protein is cleaved into S1 and S2 subunits (Figure 1). While the S1 domain recognizes the host receptor, the S2 domain is essential for the membrane fusion of the viral envelope and the endosomal membrane. To initiate membrane fusion, the S2 domain undergoes a conformational change within the central helix domain.

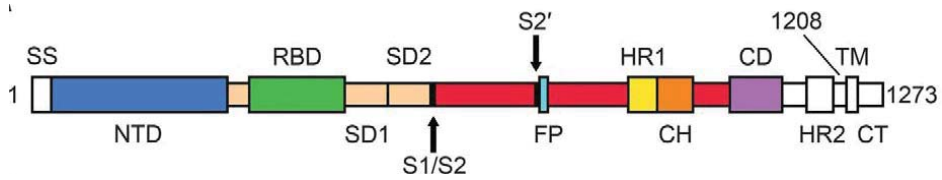

Figure 1: Schematic overview of the protein organization of the SARS-CoV-2 S protein
The sequence within the S1 subunit consists of the signal sequence (SS) and the receptor binding domain (RBD) which is the key subunit within the S protein which is relevant for binding to the human cellular receptor ACE2. The S2 subunit contains the S2 protease cleavage site (S2') followed by a fusion peptide (FP) for membrane fusion, heptad repeats (HR1 and HR2) with a central helix (CH) domain, the transmembrane domain (TM) and a cytoplasmic tail (CT); source: modified from (Wrapp et al. 2020).

Based on these features, the S protein is the prime target for vaccine development with a vaccine potentially eliciting neutralizing antibodies (nAb) that bind dominantly to the receptor-binding domain (RBD) of the S protein. Vaccine candidates selected for nonclinical testing include the following vaccine antigens:

- A secreted variant of the RBD of the SARS CoV-2 S-protein (vaccine candidate is called V5) (Kirchdoerfer et al. 2018)
- Membrane-tethered full-length S protein with two point mutations within the central helix domain. Mutation of the two amino acids to proline, (KV286-287PP) retains the S protein in an antigenically optimal prefusion conformation (vaccine candidate is called V8/V9 depending on the codon optimization used in the RNA) (Wrapp et al. 2020, Pallesen et al. 2017)

[1] Coronavirus disease (COVID-2019) situation report 141, World Health Organization; https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

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The development of *in vitro* transcribed RNA as an active platform for the use in infectious disease vaccines is based on the extensive knowledge of the company in RNA technology, which has been gained over the last decade. The core innovation is based on *in vivo* delivery of a pharmacologically optimized, antigen-coding RNA vaccine to induce robust nAbs and concomitant T-cell responses to achieve protective immunization with minimal vaccine doses (Vogel at al. 2017, Moyo et al. 2018, Pardi et al. 2017).

At BioNTech, there are three different RNA platforms under development, namely non-modified uridine-containing mRNA (uRNA), nucleoside-modified mRNA (modRNA) and self-amplifying RNA (saRNA). It is unknown today which RNA vaccine platform performs best in terms of activation and duration of a potent immune response. Therefore, BioNTech has developed a project plan evaluating the immune response of SARS-Co-V-2 vaccines based on all three platforms. The three vaccine platforms are currently tested for each antigen construct in non-clinical mouse studies to dissect the induced immunogenicity. Moreover, a GLP-compliant repeat-dose toxicity study was conducted to characterize the safety profile of each RNA platform and to assess to which extent any observed side effect is specific to the RNA platform, the vaccine dose and/or the encoded antigen. This report covers an accessory study to the REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS (LPT Study No. 38166) assessing the vaccine-induced immunogenicity seen in rats.

3.2 Objectives

The objective of this accessory study to the GLP-compliant repeat-dose toxicity study in rats (LPT Study No. 38166) was to obtain information on the immunogenicity of the administered SARS-CoV-2-S protein targeted RNA vaccines BNT162a1, BNT162b1, BNT162b2 and BNT162c1 in the rats. The elicited antibody immune response directed against the S1 domain and the RBD sub-domain was analyzed by enzyme-linked immunosorbent assay (ELISA), and the neutralizing capacity of antibodies assessed via pseudovirus neutralization test (pVNT).

3.3 Study Design

In order to obtain information on the SARS-CoV-2-S specific antibody responses induced in the GLP-compliant repeat-dose toxicity study in rats (LPT Study No. 38166), serum samples were collected from the treated main study animals at day 10 (BNT162c1) or at day 17 after first immunization (BNT162a1, BNT162b1, and BNT162b2) as well as from the treated recovery cohorts at day 31 (BNT162c1) or at day 38 (BNT162a1, BNT162b1, and BNT162b2). The corresponding study design of the *in vivo* study is summarized in Table 1. The elicited antibody immune response was analyzed by S1 domain and RBD sub-domain specific ELISA and VSV/SARS-CoV-2-S-based pVNT.

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Table 1: Study design of the GLP-compliant repeat-dose toxicity study (LPT Study No. 38166)

Test Items	• BNT162a1 (uRNA-LNP, RBD of the SARS-CoV-2 S protein) • BNT162b1 (modRNA-LNP, RBD of the SARS-CoV-2 S protein) • BNT162b2 (modRNA-LNP, mutated full-length S protein of the SARS-CoV-2 S protein) • BNT162c1 (saRNA-LNP, RBD of the SARS-CoV-2 S protein)	
Species(age)	Wistar Han rat (10-14 weeks)	
Administrations	Three (BNT162a1, BNT162b1 and BNT162b2) or two (BNT162c1) administrations on day 1, 8 and (if applicable) 15 followed by a 3-week recovery period	
Route	Intramuscular into the *M. biceps femoris*	
Dose groups	**Test Item**	**Dose level**
1	Control = Buffer	/
2	**BNT162a1** (uRNA RBD)	30 µg
3		10 µg
4	**BNT162b1** (modRNA RBD)	30 µg
5		100 µg
6	**BNT162c1** (saRNA RBD)	30 µg
7	**BNT162b2** (modRNA mutated full-length S protein)	100 µg
Satellite group (SA1)	SA1: for cytokine response analysis	3/sex/group
Group size	Group 1–7	10 (+ 5 recovery)/sex/group

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4 MATERIALS AND METHODS

4.1 Test Item

Table 2: Test serum derived from the GLP-compliant repeat-dose toxicity study (Study No. 38166).

Rat serum	Treatment and dose level	Time-point of serum generation
Group 2 (main study) (animals 31-40, 46-55)	30 µg/animal BNT162a1	Day 17
Group 2 (recovery cohort) (animals 41-45, 56-60)		Day 38
Group 3 (main study) (animals 61-70, 76-85)	10 µg/animal BNT162a1	Day 17
Group 3 (recovery cohort) (animals 71-75, 86-90)		Day 38
Group 4 (main study) (animals 91-100, 106-115)	30 µg/animal BNT162b1	Day 17
Group 4 (recovery cohort) (animals 101-105, 116-120)		Day 38
Group 5 (main study) (animals 121-130, 136-145)	100 µg/animal BNT162b1	Day 17
Group 5 (recovery cohort (animals 131-135, 146-150)		Day 38
Group 6 (main study) (animals 151-160, 166-175)	30 µg/animal BNT162c1	Day 10
Group 6 (recovery cohort) (animals 161-165, 176-180)		Day 31
Group 7 (main study) (animals 181-190, 196-205)	100 µg/animal BNT162b2	Day 17
Group 7 (recovery cohort) (animals 191-195, 206-210)		Day 38

4.2 Control Item

Table 3: Control serum derived from the GLP-compliant repeat-dose toxicity study (Study No. 38166).

Rat serum	Treatment and dose level	Time-point of serum generation
Group 1 (main study) (animals 1-10, 16-25)	Vehicle buffer control (PBS/300 mM sucrose)	Day 17
Group 1 (recovery cohort) (animals 11-15, 26-30)		Day 38

4.3 Test System

- Recombinant His-tagged SARS-CoV-2-S spike protein S1 domain coated in high-protein binding 96-well plate

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- Recombinant His-tagged SARS-CoV-2-S spike protein RBD sub-domain coated in high-protein binding 96-well plate
- HEK293T/17 (ATCC® CRL-11268™; for VSV/SARS-CoV-2-S pseudovirus generation)
- VERO 76 (ATCC® CRL-1587™; for VSV/SARS-CoV-2-S pseudovirus titration and pseudovirus neutralization testing)

4.4 Materials

Table 4: Materials

Product name	Application/specification	Article no.	Working dilution	Provider
96-well Microplate	Clear flat bottom TC-treated microplate, with lid, sterile	655160	N/A	Greiner Bio-One GmbH
96-well Microplate	Clear V bottom microplate, with lid, sterile	655180	N/A	Greiner Bio-One GmbH
96-well MaxiSorp plate	Clear Flat-Bottom Immuno Nonsterile 96-Well Plates for ELISA	439454	N/A	Thermo Fisher Scientific
50 mL tube	Conical bottom, PP, 30/115 MM, CELLSTAR®	227261	N/A	Greiner Bio-One GmbH
Cover films	ELISA	RATI6018410	N/A	VWR International GmbH
Eppendorf safe-lock tubes	0.5 mL/ 2.0 mL, Eppendorf Quality™	0030121023/ 0030120094	N/A	Eppendorf Vertrieb Deutschland GmbH
Pipette tips	ep Dualfilter T.I.P.S.®, PCR clean und sterile, 0.1–10 µL/2–100 µL/50–1000 µL/50–1250 µL/0.1–5 mL	0030077512/ 0030077547/ 0030077555/ 0030077792/ 0030077750/ 0030078616	N/A	Eppendorf Vertrieb Deutschland GmbH
Serological pipet	5 mL/10 mL/25 mL	606180 607180 760180	N/A	Greiner Bio-One GmbH
Reagent reservoir	25 mL, 100 mL	613-1179 613-1171	N/A	VWR International GmbH
Sodium Bicarbonate	ELISA, coating buffer	S5761	N/A	Sigma-Aldrich Chemie GmbH
Sodium Carbonate	ELISA, coating buffer	S7795	N/A	Sigma-Aldrich Chemie GmbH
Phosphate buffered saline (PBS), powdered	ELISA, PBS-T buffer	0780-10L	1x	VWR International GmbH
Tween 20	ELISA, PBS-T buffer	9127.1	n/a	Carl Roth GmbH & Co. KG
Casein Blocking Buffer 10x	ELISA	B6429-500 ml	1x	Sigma-Aldrich Chemie GmbH

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Product name	Application/specification	Article no.	Working dilution	Provider
TMB one ready to use-solution	ELISA	4380A	1x	Biotrend Chemiekalien GmbH
Sulphuric acid 25% EMSURE®	ELISA	1007161000	n/a	VWR International GmbH
Anti-Rabbit IgG (whole molecule) POX	ELISA	A0545-1ML	1:10000	Sigma-Aldrich
Mouse Anti-Rat IgG (H+L) HRP	ELISA	212-035-168	1:10000	Jackson ImmunoResearch
rat IgG-UNLB	ELISA	0108-01	Starting dilution 1:300	Southern Biotech
SARS-CoV-2 (2019-nCoV) Spike Antibody, Rabbit Mab	ELISA	40150-R007	1:500/ 1:1000	SinoBiological
Recombinant S protein NCP-CoV(2019-nCoV) Spike Protein (S1 Subunit, His Tag)	ELISA	40591-V08H	100 ng/ 100 µL	SinoBiological
Recombinant RBD protein 2019-nCoV Spike Protein (RBD, His Tag)	ELISA	40592-V08B	100 ng/ 100 µL	SinoBiological
Epoch Absorbance reader	ELISA	n/a	n/a	BioTek
Tecan Washer	ELISA	n/a	n/a	Tecan
Orbital shaker with heating function	ELISA	n/a	n/a	Heidolph
DMEM medium	High glucose, GlutaMAX™ Supplement, pyruvate	31966-047	N/A	Life Technologies GmbH
Fetal Bovine Serum	Non-USA origin, sterile-filtered	F7524	N/A	Sigma-Aldrich Chemie GmbH
DPBS	No calcium, no magnesium	14190-094	1 ×	Thermo Fisher Scientific
Penicillin-Streptomycin	10,000 U/mL	15140-122	33 U/mL	Gibco
2 mL tube	CRYO.S, round bottom	122278	N/A	Greiner Bio-One GmbH
Dimethyl sulfoxide	For cell culture	A3672,0100	N/A	AppliChem GmbH
Lipofectamine® LTX & PLUS™ Reagent	Pseudovirus generation	15338-100	N/A	Life Technologies GmbH
VSV-ΔG-GFP Plasmid Expression Vector System	With set of Helper Plasmids (VSV-N, VSV-P, VSV-L, VSV-G); for VSV-ΔG-GFP generation	EH1004	N/A	Kerafast, Inc.

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Product name	Application/specification	Article no.	Working dilution	Provider
VSV-G antibody,	Mouse IgG2a kappa; clone 8G5F11	EB0010	0.5 µg/mL	Kerafast, Inc.
Filter	0.45 µm Acrodisc®, Supor®	514-4123	N/A	VWR International GmbH
Incubator	Heracell 150i	N/A	N/A	Thermo Fisher Scientific
Sterile safety cabinet	Hera Safe HS18	N/A	N/A	Thermo Fisher Scientific
Live-Cell Analysis System	IncuCyte S3	N/A	N/A	Essen Bioscience
Microplate shaker	Titramax 100	N/A	N/A	Heidolph Instruments GmbH
Water bath	TW8	N/A	N/A	Julabo GmbH

Table 5: Software

Product name	Application	Provider
Excel	Animal monitoring, raw data	Microsoft Corp.
GraphPad Prism 8	Analysis of ELISA and pVNT assay	Graphpad Software Inc.

4.5 Methods

4.5.1 ELISA

Serum samples were tested in 96-well plates for their S-specific antibody concentration based on SOP-030-112 (with minor modifications as described below). Briefly, for the time points 10 days (BNT162c1) or 17 days (BNT162a1, BNT162b1 and BNT162b2, see Section 4.1) after immunization, a screening analysis was performed.

1. Coat each well of a MaxiSorp plate with 100 ng recombinant protein (SARS-CoV2 S1 subunit or RBD) per well in 100 µL coating buffer (50 mM sodium carbonate buffer [1.696 g Na_2CO_3 + 2.856 g $NaHCO_3$ ad 1 L Aqua dest.], pH 9.6)
2. Cover plates and incubate at 4°C o/n.
3. Wash three times with 300 µL/well PBS-T (9 L Aqua dest. + 1 L 10x PBS + 1 mL Tween 20).
4. Block all wells with 250 µL/well blocking buffer (900 mL Aqua dest. + 100 mL 10x Casein Blocking Buffer)
5. Incubate at 37°C for 1 h on shaker.
6. Wash three times with 300 µL/well PBS-T.
7. Dilute primary antibodies (samples and positive control) according to schedule.
8. Incubate at 37°C for 1 h on shaker.
9. Wash three times with 300 µL/well PBS-T.

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10. Dilute the secondary antibodies according to calculations.
11. Incubate at 37°C for 45 min on shaker.
12. Wash three times with 300 µL/well PBS-T.
13. Add 100 µL/well TMB substrate.
14. Incubate 8 min at RT (clear->blue).
15. Stop the reaction with 100 µL 25% sulfuric acid (blue -> yellow).
16. Read on plate reader (450 nm, reference: 620 nm).

4.5.2 Production of SARS-CoV2-S pseudotyped VSV vector

Replication-deficient vesicular stomatitis virus (VSV) that lacks the genetic information for the VSV envelope glycoprotein VSV-G but contains an open-reading frame (ORF) for green fluorescent protein (GFP) was used for SARS-CoV-2-S pseudovirus generation. VSV pseudotypes were generated according to a published protocol (Hoffmann et al. 2020).

In brief, HEK293T/17 cells cultured in DMEM supplemented with 10% FBS were transfected with a pcDNA3.1-derived expression plasmid coding for the SARS-CoV-2 spike protein (GenBank ID: QHD43416.1) with shortened cytoplasmatic tail, i.e. pSARS-CoV-2-S-CΔ19, using Lipofectamine® LTX & PLUS™ Reagent following the manufacturer's instructions. The cytoplasmatic tail was truncated for the 19 C-terminal amino acids to facilitate a more efficient integration of SARS-CoV-2-S into VSV virions analogous to SARS-CoV-S pseudotyped VSV (Fukushi et al. 2005). At 24 h post transfection, cells were inoculated with VSV-G transcomplemented VSV-ΔG-GFP vector (Indiana strain, *de novo* generated by reverse genetics from plasmid (Lawson et al. 1995)) at a multiplicity of infection (MOI) of three and incubated for 2 h at 37°C and 5% CO2. Next, the inoculum was removed, cells were washed with phosphate-buffered saline (DPBS), and standard culture medium, which contained 0.5 µg/mL anti-VSV-G antibody, was added to neutralize residual input virus. Twenty-four hours after infection, VSV/SARS-CoV-2-S pseudovirus-containing supernatants were harvested, filtered and stored at -80 °C in aliquots until further use.

4.5.3 Titration of VSV/SARS-CoV2 pseudovirus

For titration of VSV/SARS CoV-2-S pseudovirus, Vero-76 cells were thawed according to SOP-030-041, diluted to 2.67×105 cells/mL in assay medium (DMEM/10% FBS) and seeded in 96-well flat-bottom plates at 4 × 10^4 cells per well. Cells were incubated for 4 to 6 hours at 37 °C and 7.5% CO2. Meanwhile, two-fold, eight-step serial dilutions were prepared in 96-well V-bottom plates beginning with undiluted pseudovirus supernatant. Vero-76 wells were inoculated with 50 µl of the diluted pseudovirus supernatant and incubated for 16 to 24 hours at 37 °C and 7.5% CO2. Each dilution was tested in duplicate wells. After the incubation, the cell culture plates were removed from the incubator, placed in an IncuCyte Live Cell Analysis system and equilibrated for 30 minutes prior to the analysis. Whole well scanning for brightfield and GFP fluorescence was performed using a 4× objective. The number of infected GFP-

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fluorescent cells per well was plotted as a function of pseudovirus supernatant dilution using GraphPad Prism v8. Data were fitted and the fitting equation used to calculate the amount of viral supernatant needed to obtain 144 infected cells/96-well (20% excess for virus neutralization test included; see Section 4.5.4).

4.5.4 Pseudovirus Neutralization Test

For analyzing the amount of nAbs in the serum samples, sera collected at 10 days (BNT162c1) or 17 days (BNT162a1, BNT162b1 and BNT162b2, see Section 4.1) after immunization were tested using the VSV/SARS-CoV-2-S pseudovirus neutralization test (pVNT). For the pVNT assay, Vero-76 cells were thawed according to SOP-030-041, diluted to 2.67×105 cells/mL in assay medium (DMEM/10% FBS) and seeded in 96-well flat-bottom plates at 4×10^4 cells per well. Cells were incubated for 4 to 6 hours at 37 °C and 7.5% CO2. Initial dilutions of rat serum samples were prepared by adding 10 µL of serum to 50 µL assay medium in a 96-well V-bottom plate. Seven additional dilutions were subsequently prepared in two-fold dilution steps, by iteratively transferring 30 µL of diluted sera to wells containing 30 µL assay medium. VSV/SARS-CoV-2 pseudovirus was thawed and diluted to obtain 120 infected cells/25 µL (4.8×10^3 infectious units [IU]/mL). 30 µL of diluted pseudovirus (corresponds to 144 infected cells; see Section 4.5.3) was added to the wells containing the serum dilution series. The pseudovirus/serum dilution mix was incubated for 5 minutes at room temperature (RT) on a Heidolph Titramax 100 microplate shaker at 750 rpm, and additional 5 min at RT without agitation. The pseudovirus/serum dilution mix was then added to the seeded Vero-76 cells (50 µL mix per well, MOI: 0.003), followed by incubation for 16 to 24 hours at 37 °C and 7.5% CO_2. Each dilution of serum samples was tested in duplicate wells. Vero-76 cells incubated with pseudovirus in the absence of rat sera were used as positive controls. Vero-76 cells incubated without pseudovirus were used as negative controls. After the incubation, the cell culture plates were removed from the incubator, placed in an IncuCyte Live Cell Analysis system and equilibrated for 30 minutes prior to the analysis. Whole well scanning for brightfield and GFP fluorescence was performed using a 4× objective. To calculate the neutralizing titer, infected GFP-positive cell number per well was compared with the no-serum pseudovirus positive control. Mean values of the no-serum pseudovirus positive control multiplied by 0.5 represents the pseudovirus neutralization 50% (pVN50); mean values of the no-serum pseudovirus positive control multiplied by 0.1 represents the pseudovirus neutralization 90%. Serum samples with mean values below this cut-off exhibit >50% or >90% virus neutralization activity, respectively.

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5 RESULTS

The exposure of rats to the four different BNT162 vaccine candidates was evaluated via SARS-CoV-2 spike protein specific antibody responses in an accessory study to the REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS (LPT Study No. 38166). In this toxicity study rats were injected intramuscularly with different dose levels of BNT162a1, BNT162b1 or a single dose level of BNT162b2 or BNT162c1. Table 6 summarizes the treatment groups.

Table 6: Overview of treatment groups in LPT study no. 38166

Treatment group	Dose level / product	RNA platform	Antigen	Translated Protein
1			Vehicle Buffer Control	
2	30 µg BNT162a1	uRNA	V5	Secreted RBD variant with a C-terminal trimerization domain
3	10 µg BNT162a1			
4	30 µg BNT162b1	modRNA	V5	Secreted RBD variant with a C-terminal trimerization domain
5	100 µg BNT162b1			
6	30 µg BNT162c1	saRNA	V5	Secreted RBD variant with a C-terminal trimerization domain
7	100 µg BNT162b2	modRNA	V8	Membrane tethered, mutated full-length S protein

Whereas uRNA and modRNA based vaccines were administered three times one week apart (days 1, 8, 15), the saRNA based vaccine was administered only twice with one week apart (days 1, 8). The capacity of the RNA-encoded antigens to induce antibody responses was studied using ELISA and pVNT assay.

5.1 ELISA

Induced antibody responses directed against the SARS-CoV-2 spike protein S1 domain and RBD sub-domain were assessed at day 10 after two immunization rounds (BNT162c1) or day 17 after three rounds of immunization (BNT162a1, BNT162b1, and BNT162b2; Table 6), as well as from the treated recovery cohorts at day 31 (BNT162c1) or at day 38 (BNT162a1, BNT162b1, and BNT162b2). Due to the unknown strength of the elicited immune response, different dilutions of rat serum ranging from 1:100 to 1:24,300 were tested as part of an ELISA screening analysis.

Treatment of rats with each of the BNT162 vaccine candidates resulted in the formation of antibodies of the IgG isotype against the S1 domain as well as the RBD sub-domain of the SARS-CoV-2 spike protein, while these antibodies were not detected in samples

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from vehicle buffer control treated animals (Figure 2, Figure 3, Figure 4 and Figure 5). The analysis showed a weak antibody immune response for BNT162c1 treated animals at day 10 and day 31, a moderate antibody immune response for BNT162a1 treated animals at day 17 and day 38, and a strong antibody immune response for both modRNA based vaccines, BNT162b1 and BNT162b2, at day 17 and day 38, irrespective of the vaccine antigen used. Whereas for the BNT162b1 cohort the magnitude of immune activation was dose-dependent, the low-dose (10 µg/animal) BNT162a1 treated animals displayed a slightly more pronounced antibody immune response with higher titers of antigen-specific IgG in serum compared to the high-dose (30 µg/animal) treated cohort.

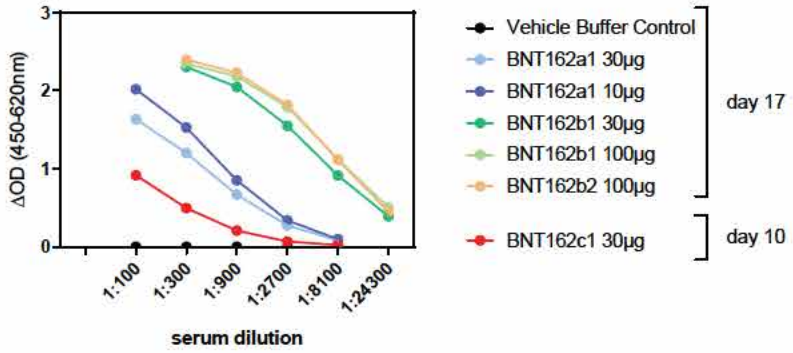

Figure 2: ELISA screening analysis of main study cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein S1 domain

ELISA was performed using serum samples collected on day 10 after two immunizations (prime/boost on days 1 and 8) with BNT162c1, or on day 17 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the S1 protein. Group mean ΔOD values of n=20 mice/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

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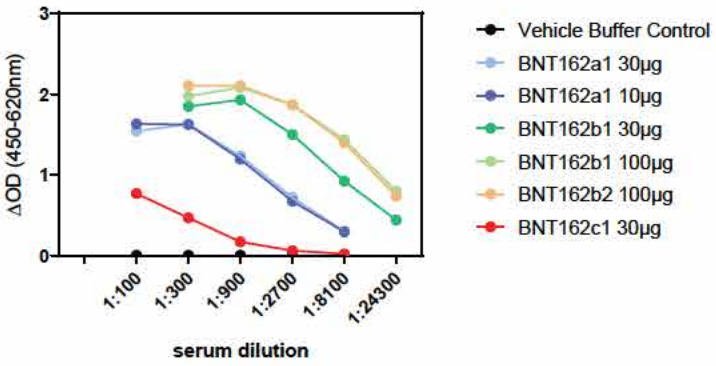

Figure 3: ELISA screening analysis of recovery cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein S1 domain

ELISA was performed using serum samples collected on day 31 after two immunizations (prime/boost on days 1 and 8) with BNT162c1, or on day 38 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the S1 protein. Group mean ΔOD values of n=20 mice/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

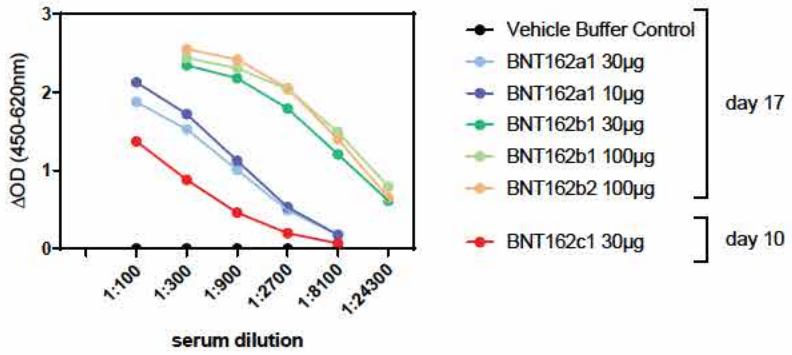

Figure 4: ELISA screening analysis of main study cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein RBD domain

ELISA was performed using serum samples collected on day 10 after two immunizations (prime/boost on days 1 and 8) with BNT162c1, or on day 17 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the RBD domain. Group mean ΔOD values of n=20 rats/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

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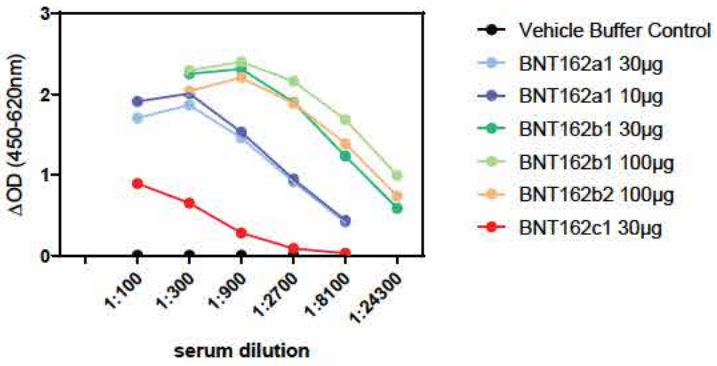

Figure 5: ELISA screening analysis of recovery cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein RBD domain

ELISA was performed using serum samples collected on day 31 after two immunizations (prime/boost on days 1 and 8) with BNT162c1, or on day 38 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the RBD domain. Group mean ΔOD values of n=20 rats/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

5.2 Pseudovirus-based Neutralization Test

To functionally characterize the elicited SARS-CoV-2 spike protein specific antibody response in rats, the neutralizing capacity of sera was assessed employing a VSV/SARS-CoV-2-S pseudovirus system in conjunction with Vero 76 cells as target. Vero 76 cell express endogenous angiotensin-converting enzyme 2 (ACE2), the identified entry receptor for SARS-CoV-2 (Hoffmann et al. 2020). Sera of ten representative animals per cohort and time-point (generated from n=5 male and n=5 female rats) were analyzed.

Treatment of rats with each of the BNT162 vaccine candidates resulted in the formation of neutralizing antibodies protecting Vero 76 cells against pseudovirus infection (titer resulting in 50% pseudovirus neutralization in Figure 6 and Figure 7; titer resulting in 90% pseudovirus neutralization in Figure 8 and Figure 9). In contrast, no neutralizing activity was associated with serum samples generated from vehicle buffer control treated animals. Neutralizing antibody titers in vaccinated animals increased over time with the recorded neutralizing activity being consistent with the ELISA data shown in Section 5.1. Whereas sera from BNT162c1 treated animals display weak neutralizing activity both at days 10 and 31, sera from BNT162a1 treated animals display moderate neutralizing activity at day 17 that is significantly augmented at day 38. The strongest pseudovirus neutralization effect is mediated by sera generated from BNT162b1- and BNT162b2-treated rats. In case of both modRNA-based vaccines, BNT162b1 and

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BNT162b2, neutralizing antibody titers resulting in 50% pseudovirus neutralization exceeded the upper limit of quantification (ULOQ) of a reciprocal titer of 1536 in more than 8 out of ten animals at day 38.

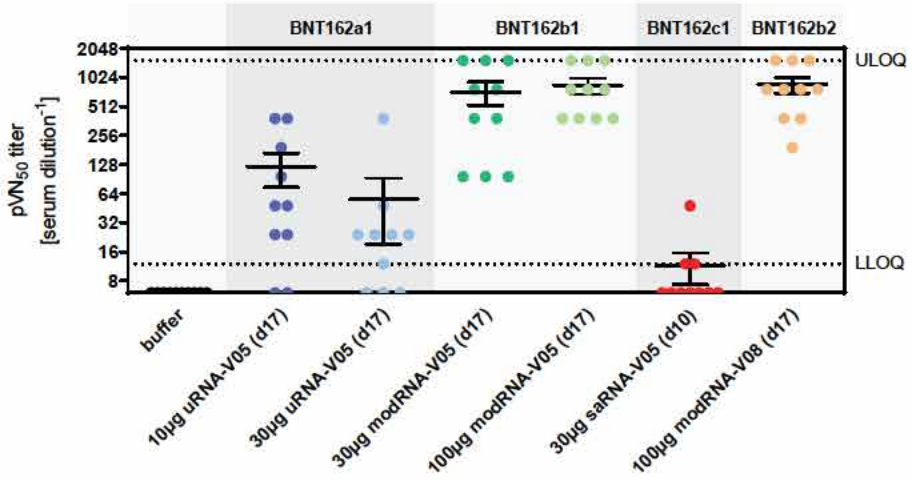

Figure 6: Pseudovirus neutralization activity of main study cohort sera plotted as pVN_{50} titer

Serum samples were collected on day 10 (BNT162c1, red dots) or day 17 (all other cohorts) after first immunization of the main study animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 50% pseudovirus neutralization (pVN_{50}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

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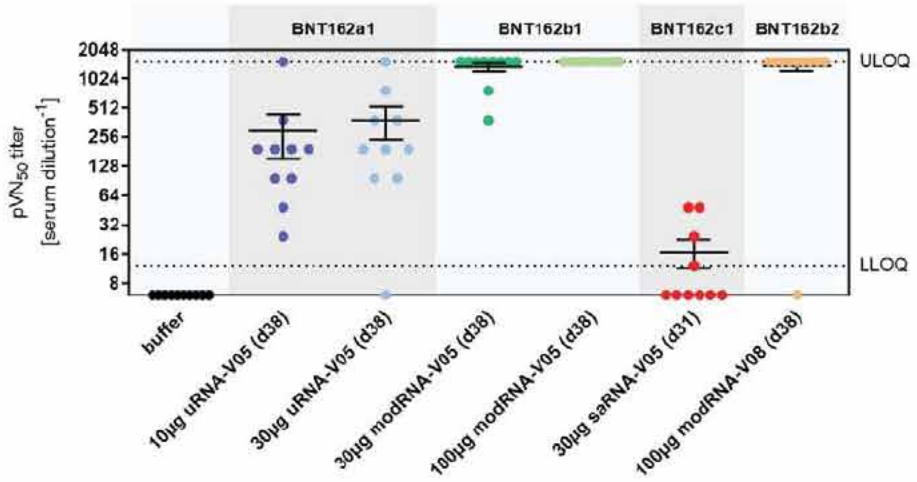

Figure 7: Pseudovirus neutralization activity of recovery cohort sera plotted as pVN_{50} titer

Serum samples were collected on day 31 (BNT162c1, red dots) or day 38 (all other cohorts) after first immunization of the recovery cohort animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 50% pseudovirus neutralization (pVN_{50}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

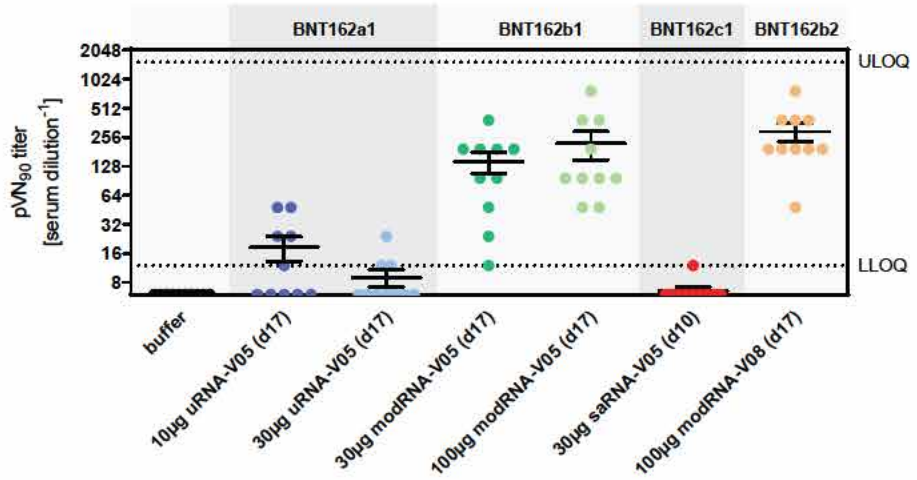

Figure 8: Pseudovirus neutralization activity of main study cohort sera plotted as pVN_{90}

Serum samples were collected on day 10 (BNT162c1, red dots) or day 17 (all other cohorts) after first immunization of the main study animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 90% pseudovirus neutralization (pVN_{90}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

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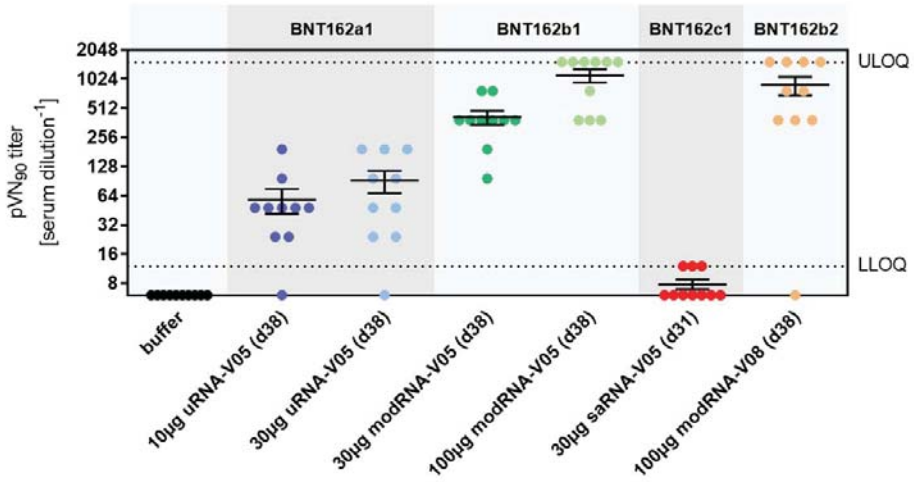

Figure 9: Pseudovirus neutralization activity of recovery cohort sera plotted as pVN_{90}

Serum samples were collected on day 31 (BNT162c1, red dots) or day 38 (all other cohorts) after first immunization of the recovery cohort animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 90% pseudovirus neutralization (pVN_{90}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

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6 CONCLUSION

The available data demonstrates that all BNT162 vaccine candidates elicited a SARS-CoV-2 spike protein specific antibody response directed against the S1 domain and the RBD sub-domain. Antibody responses detected via ELISA directly translated into neutralizing activity as seen in the VSV/SARS-CoV2-S pseudovirus neutralization test with BNT162 vaccines showing higher antigen-specific antibody titers also displaying more pronounced virus neutralization effect. A comparison of the three RNA platforms with regard to their immunogenicity in rats may not be fully predictive for how they may perform relative to each other in human due to species-specific differences in immunity mechanisms.

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7 DOCUMENT HISTORY

First version / no change.

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9 APPENDIX

Appendix 1: pVNT raw data

Table 7: Pseudovirus neutralization activity of sera generated from male rats in group 1

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		1	2	3	4	5	Virus control	Cell control	VN50
1:12	A	98,6	108,5	112,0	93,2	105,3	100	0	50
1:24	B	90,4	81,9	91,1	96,8	100,2			
1:48	C	97,9	105,3	99,1	100,3	97,3			
1:96	D	115,9	95,9	86,6	92,8	91,1			
1:192	E	95,3	99,5	82,0	70,8	78,2			
1:384	F	98,3	63,2	69,4	33,7	31,8			
1:768	G	86,9	56,3	54,5	55,9	40,6			
1:1536	H	84,0	81,2	76,3	60,8	61,9			

Table 8: Pseudovirus neutralization activity of sera generated from female rats in group 1

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		16	17	18	19	20	Virus control	Cell control	VN50
1:12	A	113,7	138,3	134,2	99,3	104,8	100	0	50
1:24	B	112,1	108,5	113,6	97,8	111,1			
1:48	C	125,4	116,5	118,4	113,6	111,6			
1:96	D	122,3	67,9	72,3	67,1	91,5			
1:192	E	111,8	66,5	74,2	72,5	63,2			
1:384	F	119,7	77,2	46,3	53,6	54,6			
1:768	G	123,2	97,3	54,6	70,8	66,9			
1:1536	H	97,3	75,1	84,3	77,5	56,4			

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Table 9: Pseudovirus neutralization activity of sera generated from male rats in group 2

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		31	32	33	34	35	Virus control	Cell control	VN50
1:12	A	90,8	10,1	8,5	100,0	18,1	100	0	50
1:24	B	89,1	38,4	31,9	119,3	39,9			
1:48	C	112,8	76,5	64,8	123,0	64,2			
1:96	D	118,6	75,9	61,1	104,4	62,3			
1:192	E	97,3	61,1	39,4	74,2	65,7			
1:384	F	99,3	62,6	46,8	77,1	64,8			
1:768	G	111,1	104,6	100,3	69,3	86,7			
1:1536	H	110,8	102,6	82,9	72,9	65,7			

Table 10: Pseudovirus neutralization activity of sera generated from female rats in group 2

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		46	47	48	49	50	Virus control	Cell control	VN50
1:12	A	28,7	99,8	9,9	15,3	0,8	100	0	50
1:24	B	53,8	122,7	37,7	34,1	1,5			
1:48	C	75,3	133,1	63,3	50,0	14,4			
1:96	D	82,8	126,1	55,3	62,6	26,4			
1:192	E	110,2	131,2	72,1	86,5	39,0			
1:384	F	88,0	66,3	45,4	57,4	35,4			
1:768	G	114,0	97,8	86,3	88,3	60,0			
1:1536	H	85,4	74,7	78,4	78,5	37,9			

Table 11: Pseudovirus neutralization activity of sera generated from male rats in group 3

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		61	62	63	64	65	Virus control	Cell control	VN50
1:12	A	20,3	72,8	6,0	4,4	14,9	100	0	50
1:24	B	43,2	84,4	31,3	8,1	41,3			
1:48	C	58,9	95,6	47,5	19,9	60,0			
1:96	D	78,6	99,6	73,0	33,6	83,4			
1:192	E	84,6	106,9	96,9	53,9	92,1			
1:384	F	95,9	109,3	87,1	62,9	95,2			
1:768	G	84,2	91,5	93,4	60,6	95,2			
1:1536	H	91,1	94,0	90,3	85,9	96,1			

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Table 12: Pseudovirus neutralization activity of sera generated from female rats in group 3

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		76	77	78	79	80	Virus control	Cell control	VN50
1:12	A	1,7	10,0	63,3	0,0	0,4	100	0	50
1:24	B	5,8	25,1	86,7	1,4	2,3			
1:48	C	12,5	44,6	101,0	6,0	6,2			
1:96	D	24,7	58,1	103,5	12,2	20,5			
1:192	E	36,1	76,1	96,1	24,9	34,2			
1:384	F	58,5	90,9	99,0	48,5	43,1			
1:768	G	72,6	91,7	98,8	51,2	62,7			
1:1536	H	76,3	98,5	90,3	65,6	64,5			

Table 13: Pseudovirus neutralization activity of sera generated from male rats in group 4

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		91	92	93	94	95	Virus control	Cell control	VN50
1:12	A	0,0	0,0	2,9	0,6	1,0	100	0	50
1:24	B	0,0	0,3	5,2	1,0	1,6			
1:48	C	1,0	0,6	21,7	0,3	1,6			
1:96	D	3,2	1,9	22,7	3,6	5,2			
1:192	E	20,7	2,3	60,2	4,9	17,2			
1:384	F	45,6	11,3	69,3	16,8	31,1			
1:768	G	72,5	27,2	95,5	31,4	65,7			
1:1536	H	112,3	35,6	134,6	55,3	99,4			

Table 14: Pseudovirus neutralization activity of sera generated from female rats in group 4

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		106	107	108	109	110	Virus control	Cell control	VN50
1:12	A	0,7	0,3	2,4	0,0	0,7	100	0	50
1:24	B	2,9	0,1	12,7	0,1	0,1			
1:48	C	7,9	0,4	24,4	0,4	0,8			
1:96	D	28,6	1,0	39,2	0,7	1,6			
1:192	E	50,7	6,0	61,5	2,4	6,9			
1:384	F	66,8	16,9	63,0	7,1	15,8			
1:768	G	86,1	34,8	75,4	16,7	31,6			
1:1536	H	79,5	55,2	74,6	31,2	42,3			

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Table 15: Pseudovirus neutralization activity of sera generated from male rats in group 5

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		121	122	123	124	125	Virus control	Cell control	VN50
1:12	A	0,0	0,2	0,7	0,2	0,7	100	0	50
1:24	B	0,9	0,0	0,0	0,0	0,9			
1:48	C	5,7	0,9	0,0	0,9	1,5			
1:96	D	16,1	4,6	2,0	1,1	9,6			
1:192	E	29,6	13,5	10,4	5,2	21,3			
1:384	F	47,8	23,9	19,6	8,0	37,6			
1:768	G	66,5	40,2	40,2	25,9	54,1			
1:1536	H	76,7	52,0	67,8	40,9	65,9			

Table 16: Pseudovirus neutralization activity of sera generated from female rats in group 5

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		136	137	138	139	140	Virus control	Cell control	VN50
1:12	A	0,0	0,2	0,0	0,0	0,4	100	0	50
1:24	B	0,4	0,0	0,9	0,0	0,0			
1:48	C	0,4	0,4	2,4	0,2	0,0			
1:96	D	4,4	2,9	11,0	0,2	0,0			
1:192	E	17,6	6,4	25,3	3,3	0,4			
1:384	F	19,6	12,3	28,6	4,2	2,0			
1:768	G	61,5	33,7	71,1	20,0	8,6			
1:1536	H	75,1	51,3	85,0	37,7	26,2			

Table 17: Pseudovirus neutralization activity of sera generated from male rats in group 6

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		151	152	153	154	155	Virus control	Cell control	VN50
1:12	A	27,4	105,2	62,6	108,1	122,0	100	0	50
1:24	B	54,0	106,8	67,8	108,1	124,8			
1:48	C	80,5	111,9	75,2	109,1	106,6			
1:96	D	98,4	107,1	81,0	115,5	99,7			
1:192	E	91,5	113,3	73,7	92,9	115,5			
1:384	F	87,7	104,3	94,0	100,1	94,3			
1:768	G	98,9	91,0	88,7	95,7	97,0			
1:1536	H	93,2	85,6	90,9	95,1	90,5			

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Table 18: Pseudovirus neutralization activity of sera generated from female rats in group 6

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		166	167	168	169	170	Virus control	Cell control	VN50
1:12	A	143,0	101,3	134,0	4,0	31,0	100	0	50
1:24	B	90,6	109,4	104,8	14,6	61,7			
1:48	C	89,5	90,8	101,5	31,7	80,6			
1:96	D	90,7	89,6	106,1	52,1	93,8			
1:192	E	90,3	86,8	93,5	66,8	99,5			
1:384	F	96,0	104,4	101,0	77,5	92,4			
1:768	G	89,7	97,3	101,2	84,5	101,2			
1:1536	H	89,0	91,5	94,9	87,0	89,8			

Table 19: Pseudovirus neutralization activity of sera generated from male rats in group 7

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		181	182	183	184	185	Virus control	Cell control	VN50
1:12	A	0,2	0,0	0,0	0,0	0,0	100	0	50
1:24	B	0,2	1,2	0,7	0,0	0,0			
1:48	C	2,1	0,2	0,7	0,5	1,2			
1:96	D	11,5	0,0	0,9	1,2	0,2			
1:192	E	29,7	3,3	5,9	9,9	2,1			
1:384	F	63,6	16,3	22,9	23,6	10,8			
1:768	G	101,1	46,2	54,4	57,7	37,5			
1:1536	H	131,2	88,8	91,4	91,2	77,3			

Table 20: Pseudovirus neutralization activity of sera generated from female rats in group 7

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		196	197	198	199	200	Virus control	Cell control	VN50
1:12	A	0,0	0,0	0,2	0,0	0,0	100	0	50
1:24	B	0,0	0,2	0,2	0,0	0,0			
1:48	C	0,0	0,4	0,9	0,0	0,0			
1:96	D	0,0	0,0	1,3	1,1	0,0			
1:192	E	0,0	0,2	4,9	0,7	1,8			
1:384	F	2,9	5,3	15,5	4,0	9,9			
1:768	G	9,9	16,1	44,4	12,2	20,8			
1:1536	H	41,8	38,7	85,3	22,1	58,6			

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Final Report Amendment 1

17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Testing Facility Study Number: 20GR142

Alternative Test Article Identifier(s):

PF-07302048: Generic number for COVID-19 vaccine program

BNT162b2 (V9): BNT162b2 (Version 9); RBP020.2; PF-07305885

BNT162b3c: BNT162b3; RBP020.8; PF-07315256

TESTING FACILITY:

Pfizer Worldwide Research & Development
Drug Safety Research & Development
Eastern Point Road
Groton, CT 06340 USA

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SIGNATURES

The final report has been amended to clarify and correct the data and/or interpretation of the results following issuance on 13 Nov 2020.

Study Director

s 22

Quality Assurance Statement Signature

The signature for the following individual applies only to the Groton, CT Quality Assurance Statement contained in this study report.

s 22

Regulatory Quality Assurance-Good Laboratory Practices, Pfizer, Groton CT.

For signatures see the Document Approval Record located on the last page of this report amendment.

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1. AMENDED TEXT

Section: GLP Compliance Statement

Justification for revision(s): Text is being revised based on feedback from regulatory authorities to clarify that manufacturing of the test articles was conducted non-GMP but characterization of the test articles was conducted under GMP conditions, and that serology analysis was conducted under Good Clinical Laboratory Practice (GCLP).

Current:

This study was conducted in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies regulations as set forth in the Code of Federal Regulations (21 CFR Part 58) with the exceptions of the analyses of alpha-1 acid glycoprotein (A1AGP) and alpha-2-macroglobulin (A2M), and testing performed on the test articles BNT162b2 (Version 9 [V9]) and BNT162b3c which were under non-GLP and non-GMP conditions, respectively. These parameters were conducted under non-GLP and non-GMP conditions and were performed according to fit-for-purpose methods. These exceptions did not have an impact on the integrity or data interpretation of the study.

Amended To:

This study was conducted in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies regulations as set forth in the Code of Federal Regulations (21 CFR Part 58) with the exceptions of the analyses of alpha-1 acid glycoprotein (A1AGP) and alpha-2-macroglobulin (A2M) which were under non-GLP conditions. Manufacturing of the test articles BNT162b2 (Version 9 [V9]) and BNT162b3c was conducted under non-GMP conditions, while characterization of the test articles was conducted under GMP conditions. Serology analysis was performed in accordance with Good Clinical Laboratory Practice (GCLP). All parameters that were conducted under non-GLP and non-GMP conditions were performed according to fit-for-purpose methods. These exceptions did not have an impact on the integrity or data interpretation of the study.

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Regulatory Quality Assurance

Quality Assurance Statement

Title: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study: 20GR142

In accordance with Pfizer policies and Regulatory Quality Assurance procedures for Good Laboratory Practice (GLP), the conduct of this study has been inspected and/or audited as follows. The Individual Quality Assurance Statement for study phase(s) conducted at other site(s) are contained within this report.

Phase Inspected	Audit/Inspection Date GMT	Reporting Date GMT
Report Amendment 1: Nonclinical Study	17-Dec-2020 to 17-Dec-2020	17-Dec-2020

In addition Routine Facility and Process audits are conducted in accordance with RQA SOPs and Site Monitoring Plans.

s 22

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Document Approval Record

Document Name:	Report Amendment
Document Title:	Study 20GR142 Report Amendment 1

Signed By:	Date(GMT)	Signing Capacity
s 22	17-Dec-2020 21:25:01	Quality Assurance Approval
s 22	17-Dec-2020 21:28:51	Author Approval

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17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Testing Facility Study Number: 20GR142

Alternative Test Article Identifier(s):

PF-07302048: Generic number for COVID-19 vaccine program

BNT162b2 (V9): BNT162b2 (Version 9); RBP020.2; PF-07305885

BNT162b3c: BNT162b3; RBP020.8; PF-07315256

TESTING FACILITY:
Pfizer Worldwide Research & Development
Drug Safety Research & Development
Eastern Point Road
Groton, CT 06340 USA

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SIGNATURES

I approve the report and confirm that the study was conducted in compliance with GLP regulations with the exceptions noted (see GLP Compliance Statement). My interpretation and conclusion of the data accurately reflects the interpretation of the Contributing Scientists and Principal Investigators.

Study Director
s 47

Quality Assurance Statement Signature

The signature for the following individual applies only to the Groton, CT Quality Assurance Statement contained in this study report.

s 47
Regulatory Quality Assurance-Good Laboratory Practices, Pfizer, Groton CT.

For signatures see the Document Approval Record located on the last page of this report.

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OTHER STUDY PERSONNEL

The following personnel were involved in the conduct of this study:

Comparative Medicine Activities: Ophthalmology Examinations: Study Technician(s): Study Scientist: Study Toxicologist: Test Formulations Coordinator: Formulator: Clinical Pathology Coordinator: Necropsy/Histology Coordinator: Biostatistician: Safety Biomarkers and Translational Sciences Scientist: Principal Investigators: Serum Antibody Sample Analysis: Clinical Pathologist: Anatomic Pathologist: Peer Review Pathologist	s 22

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GLP COMPLIANCE STATEMENT

This study was conducted in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies regulations as set forth in the Code of Federal Regulations (21 CFR Part 58) with the exceptions of the analyses of alpha-1 acid glycoprotein (A1AGP) and alpha-2-macroglobulin (A2M), and testing performed on the test articles BNT162b2 (Version 9 [V9]) and BNT162b3c which were under non-GLP and non-GMP conditions, respectively. These parameters were conducted under non-GLP and non-GMP conditions and were performed according to fit-for-purpose methods. These exceptions did not have an impact on the integrity or data interpretation of the study.

ANIMAL WELFARE COMPLIANCE

This study was conducted in accordance with the current guidelines for animal welfare (National Research Council Guide for the Care and Use of Laboratory Animals, 2011). The procedures used in this study were reviewed and approved by the Institutional Animal Care and Use Committee.

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ABSTRACT

BNT162b2 (Version 9 [V9]) and BNT162b3c are candidate COVID-19 vaccines, which are based on a lipid nanoparticle (LNP)-RNA platform and express the SARS-CoV-2 spike protein or its derivatives. The objective of this study was to determine the toxicity and development of a specific immune response to the antigen in each of the vaccine candidates following intramuscular (IM) administration once weekly for a total of 3 doses to Wistar Han (Crl:WI[Han]) rats. The reversibility of effects was evaluated following a 3-week recovery phase.

IM administration of BNT162b2 (V9) and BNT162b3c at 30 µg RNA/dose once weekly for a total of 3 doses to Wistar Han rats was tolerated without evidence of systemic toxicity and produced nonadverse inflammatory changes consistent with expected immune responses to vaccines.

At the conclusion of the dosing phase, test article-related immune responses to both vaccines were evident as transient edema and erythema at the injection site after each dose, transient higher mean body temperatures compared with controls after each dose, higher white blood cell count (primarily involving neutrophils, monocytes and large unstained cells), and changes in acute phase reactants (higher [alpha-1 acid glycoprotein and alpha-2-macroglobulin and fibrinogen] and lower [lower albumin and albumin:globulin (AG) ratios] acute phase proteins. These test article-related changes were fully reversed after the recovery phase, with the exception of higher red cell distribution width, higher globulins, and lower AG ratio.

Changes secondary to inflammation included lower mean body weight, lower mean food consumption, transiently lower reticulocyte counts, and minor lower red cell mass at the conclusion of the dosing phase. These changes fully resolved in the recovery phase.

At the conclusion of the dosing phase, nonadverse test article-related microscopic findings consistent with immune activation and an inflammatory response included mixed cell inflammation and edema of the injection sites (which correlated with macroscopic observations of abnormal color, dark/pale and abnormal consistency, firm), increased cellularity of plasma cells and germinal centers of the draining and inguinal lymph nodes (which correlated with macroscopic observation of abnormal size, enlarged), increased cellularity of hematopoietic cells and germinal centers of the spleen (which correlated with macroscopic observation of abnormal size, enlarged and increased spleen weights), and increased cellularity of hematopoietic cells in the bone marrow were noted. These test article-related changes fully recovered, except for partial recovery of enlarged draining and inguinal lymph nodes and microscopic findings of inflammation at the injection sites, increased cellularity of plasma cells and germinal centers in the draining and inguinal lymph nodes and increased cellularity of the germinal centers in the spleen.

In addition, test article-related vacuolation of the periportal hepatocytes in the liver was observed, in the absence of biochemical evidence of liver injury, and may be related to hepatic clearance of PEGylated lipids that are part of the LNP formulation. At the end of the 3-week recovery phase, this finding was completely recovered.

Administration of 3 once weekly doses of BNT162b2 (V9) or BNT162b3c elicited SARS-CoV-2 neutralizing antibody responses in both males and females at the end of the dosing and recovery phases of the study. SARS-CoV-2 neutralizing antibody responses were not observed in animals prior to vaccine administration or in saline-administered control animals.

In conclusion, BNT162b2 (V9) and BNT162b3c administered via intramuscular injection once weekly for a total of 3 doses to Wistar Han (Crl:WI[Han]) rats was tolerated without evidence of systemic toxicity, generated a SARS-CoV-2 neutralizing antibody response, and produced nonadverse changes consistent with an immune or inflammatory response at the conclusion of the dosing phase. At the end of the 3-week recovery phase, full or partial recovery of all findings was observed. Other nonadverse findings included vacuolation in the liver which may be related to hepatic clearance of PEGylated lipids and was noted at the conclusion of the dosing phase and completely recovered. The findings in this study are consistent with those typically associated with the intramuscular administration of LNP-encapsulated mRNA vaccines. Animals administered BNT162b2 (V9) or BNT162b3c elicited SARS-CoV-2 neutralizing antibody responses at the end of the dosing and recovery phases of the study.

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1. INTRODUCTION AND OBJECTIVE

BNT162b2 (Version 9 [V9]) and BNT162b3c are candidate COVID-19 vaccines, which consist of an LNP-encapsulated RNA encoding the SARS-CoV-2 spike protein or its derivatives. The objective of this study was to determine the toxicity and development of a specific immune response to the antigens in each of the vaccine candidates following administration of intramuscular (IM) doses once weekly for a total of 3 doses to Wistar Han (Crl:WI[Han]) rats. The reversibility of effects was evaluated following a 3-week recovery phase.

2. STUDY RATIONALE

BNT162b2 (V9) and BNT162b3c were evaluated at the highest intended dose (doses up to 30 µg of RNA administered twice) in clinical trials. Therefore, 3 IM administrations of each vaccine at 30 µg RNA for a total of 3 doses were evaluated in the current study in rats on a more accelerated schedule (once weekly) compared to the clinic. The IM route is the clinical route of administration. The rat is a standard rodent test species for use in toxicity studies and has been shown to generate an immune response to very similar types of RNA-based vaccines.

3. MULTI-SITE INFORMATION

Microscopic examination was conducted at Pfizer, Pearl River. Evaluation of Clinical Laboratory parameters was conducted at Pfizer, Pearl River. The analysis for detection of neutralizing antibody titers (serology) to wild type live SARS-CoV-2 virus was conducted at VisMederi, Srl (Siena, Italy).

3.1. Communication Method

The Principal Investigator was responsible for informing the Study Director of any deviations to the protocol or Standard Operating Procedures (SOPs) and unexpected events as they occurred during the respective study phase. Other issues were communicated at the end of the respective study phase prior to the issuance of the report.

3.2. Reporting Method

Clinical Pathology and Anatomic Pathology Principal Investigator's reports are appended to the final study report. Data and interpretation are integrated into the final study report. The Serology Principal Investigator's report is integrated and appended to the final study report.

Methods for each phase are described in the SOP of the respective test site.

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4. CONTACT INFORMATION

Pfizer Lead Quality Assurance (QA)[a]	s 22 Pfizer Regulatory Quality Assurance-Good Laboratory Practices (RQA-GLP) s 22 Groton, CT 06340 Telephone: s 22 Email: s 22
Pfizer Test Site QA[a]	s 22 Pfizer Regulatory Quality Assurance-Good Laboratory Practices (RQA-GLP) s 22 401 N. Middletown Road Pearl River, NY 10965 Telephone: s 22 Email: s 22
CRO Test Site[b]	s 22 s 22 Email: s 22

CRO = Contract Research Organization.

a. The Pfizer lead and test site QA monitored applicable study phases, audited the final study or Principal Investigator (PI) report(s), and issued QA statement(s) for work conducted at their respective test sites according to RQA-GLP SOPs. Lead QA was responsible for coordination to ensure appropriate overall study monitoring.

b. The CRO test site QA monitored the phase, audited the CRO Principal Investigator's report, and issued a QA Statement according to CRO test site QA SOPs.

5. MATERIALS AND METHODS

For phases of the study conducted at Pfizer Worldwide Research & Development (Pfizer WRD), Groton, CT, details of methods described below are included in the Standard Operating Procedures of Pfizer WRD, Groton, CT and in the SOPs of the respective Pfizer WRD facility conducting those activities.

Minor deviations from the protocol and/or current standard operating procedures occurred and did not affect the quality, integrity or interpretations of the data or the conclusions of the study. The deviations are documented in the study records and are discussed in the appropriate section of the report.

5.1. Study Schedule

Study Initiation Date (date protocol signed):	23 Jun 2020
Experimental Start Date (first day of study-specific data collection):	24 Jun 2020
First Day of Dosing (Day 1):	06 Jul 2020
First Day of Recovery Phase:	23 Jul 2020
Dosing Phase Necropsy (first 10 animals/sex/group):	22 Jul 2020
Recovery Phase Necropsy (remaining animals):	13 Aug 2020
Experimental Completion Date (last day of study-specific data collection):	13 Aug 2020

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5.2. Test and Control Articles

5.2.1. Test Articles

5.2.1.1. BNT162b2 (V9)

Test Article Number:	BNT162b2 (V9)
Lot Number:	COVVAC/270320
Manufacturer:	Polymun
Composition	0.5 mg/mL RNA encoding the full SARS-CoV-2 Spike (S) P2 variant protein
Expiration Date:	27 Sep 2020
Storage Conditions:	Frozen at -80°C, protected from light
Composition:	See Certificate of Analysis in Appendix C.

5.2.1.2. BNT162b3c

Test Article Number:	BNT162b3c
Lot Number:	BCV/040620
Manufacturer:	Polymun
Composition	0.5 mg/mL RNA encoding Membrane-anchored, trimerized variant of the RBD of the SARS-CoV-2 S protein
Expiration Date:	04 Dec 2020
Storage Conditions:	Frozen at -80°C, protected from light
Composition:	See Certificate of Analysis in Appendix C.

5.2.2. Control Article(s)

5.2.2.1. Vehicle

A solution of 0.9% sterile saline was used to dose the control animals (Group 1).

Excipient:	0.9% sterile saline
Lot Number:	J8L247
Expiration Date:	31 Mar 2021

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5.2.3. Test Article Formulation and Analyses

Test Article Numbers: BNT162b2 (V9) and BNT162b3c

Type of Formulation:	Suspension
Method of Preparation:	Thawing of frozen formulation
Frequency of Preparation:	06 Jul 2020, 13 Jul 2020, and 20 Jul 2020
Storage:	Room temperature, protected from light
Formulation Handling at Time of Dispensing for Dosing:	Formulations were gently inverted to mix to ensure uniformity prior to dose administration
Stability:	2 hours from the time thaw was completed[a]
Concentration Analyses:	Not applicable; material was utilized as supplied

a. Reference: DOSAGE AND ADMINISTRATION INSTRUCTIONS FOR BNT162 (PF-07302048) VACCINE, 0.5 MG/ML (C459-INX100407124-V4.0). NOTE: Although the information in this reference document is not specific to the test articles utilized in this study, it was for the same platform of vaccines and was deemed appropriate for use.

5.3. Test System

Species:	Rat
Strain/Breed/Origin:	Wistar Han (Crl:WI[Han])
Animal Use Protocol (AUP) Number:	GTN-2011-00314
Source:	Charles River Laboratories Raleigh, NC
Age at Dose Initiation:	9 weeks
Weight at Dose Initiation:	Males: 243.1 grams - 291.6 grams Females: 172.9 grams - 209.5 grams

5.3.1. Acclimation

Animals were acclimated to the laboratory environment for a minimum of 13 days prior to initiation of dosing.

5.3.2. Identification

Animals were identified by a radio frequency identification device (RFID) implanted by the vendor (subscapular region) that was associated with a unique identification number for each animal. Each cage was labeled with a cage card for each animal in the cage.

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5.3.3. Allocation and Randomization

Clinically acceptable animals were allocated to study groups following the review of data collected prior to the initiation of dosing and using a computer-assisted randomization procedure based on body weights.

5.4. Housing and Environmental Conditions

Caging:	Housed individually in suspended cages
Bedding:	Enrich-n'Pure®, The Andersons, Inc.
Temperature:	68°F-79°F
Humidity:	30%-70%
Lighting:	Approximate 12-hour light, 12-hour dark cycle.
Water:	Municipal drinking water, further purified by reverse osmosis, was provided ad libitum.
Diet:	Certified Irradiated Rodent Diet 5002 (PMI Feeds Inc.) was provided ad libitum. Lot number(s) are included in the raw data.

There are no known contaminants in the food or water that interfered with the quality or integrity of the data.

5.5. Experimental Groups

Group Number	Test Article or Vehicle Dose (µg RNA/Dose Day)	Dose Volume (µL/injection site)[a]	Animal Numbers	
			Males	Females
1	0[b]	60	1-15	46-60
2	30[c]	60	16-30	61-75
3	30[d]	60	31-45	76-90

a. Each animal received a single intramuscular injection on each dose day.
b. Sterile saline.
c. BNT162b2 (V9).
d. BNT162b3c.

Doses were administered by a single intramuscular injection (60 µL) on each dosing day (Days 1, 8, and 15) into the left hindlimb quadriceps muscle.

The first 10 animals/sex/group, by ascending animal order, were designated for necropsy at the end of the dosing phase. The remaining 5 animals were retained for the recovery phase.

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5.6. Observations and Measurements

5.6.1. Clinical Observations/Measurements

General (Cageside) Clinical Observations:	**Days of Study**	**Time Points**
	Prior to the Initiation of Dosing (PID)	Once daily
	Nondosing Days (Dosing Phase)	Twice daily, except on days when detailed clinical observations were performed, then only once daily
	Dosing Days (Dosing Phase)	Predose, except on days that predose detailed clinical observations were performed, 4 hours after the last animal was dosed, and at the end of the workday. On 06 Jul 2020 (Day 1), clinical signs were not conducted at the end of the workday for Animals 001-090.
	Recovery Phase Days	Twice daily
Detailed Clinical Observations:	Detailed clinical observations were performed twice prior to the initiation of dosing, twice weekly at approximately the same time body weights were performed, and on the day(s) of necropsy.	
Body Weight:	All animals were weighed twice prior to the initiation of dosing on PID Phase Days 1 and 6, predose on Dosing Phase Days 1, 8, and 15; on Dosing Phase Days 4 and 11 (nondosing), and a fasted weight was collected just prior to scheduled necropsy. Body weights were collected on Recovery Phase Days 1, 4, 8, 11, 15, 18, and 21.	
Food Consumption:	Quantitative food consumption was recorded on Dosing Phase Days 4, 8, 11, and 15 and on Recovery Phase Days 4, 8, 11, 15, 18, and 21.	
Ophthalmology:	Ophthalmic examinations were performed once prior to the initiation of dosing (following randomization) on PID Phase Days 7/8 (males/females) and on Dosing Phase Days 15/16 (males/females). Recovery animals were not examined at the end of the recovery phase. See the Ophthalmology Report in Appendix B for complete materials and methods.	
Injection Site Scoring (Dermal Assessment):	Injection sites were observed during the dosing phase once predose and approximately 4 and 24 hours postdose on all animals. Animals with a score of 2 or greater at 24 hours postdose had additional evaluations at 48 and 72 hours postdose. Animals with a continued score of 2 or greater at 72 hours postdose had additional evaluations at 120 and 144 hours postdose. After dosing on Day 15, a 72-hour postdose evaluation was conducted on recovery animals only. Injection site score was recorded according to a standardized rating scale (Draize, 1959). On Dosing Phase Day 1 (06 Jul 2020), predose dermal assessments were collected on all animals for right-side injection sites (noninjection site), and at 4 hours postdose, dermal assessments were collected on Animals 1-7, 9 (Group 1, Males), and 46-58 (Group 1, Females) for right-side injection sites (noninjection site).	
Body Temperature:	Body temperature was collected on all animals once prior to the initiation of dosing on PID Phase Day 6, predose on Dosing Phase Days 1, 8, and 15, and at approximately 4 and 24 hours postdose from all animals.	

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5.6.2. Clinical Laboratory Measurements

Schedule for Collection of Samples for Clinical Laboratory Measurements			
Parameter	**Day of Study**		
	Dosing Phase		**Recovery Phase**
	Day 4	Day 17[e]	Day 22
Hematology	X[a,c]	X[c]	X[c]
Coagulation	NA	X[c]	X[c]
Clinical Chemistry (Core Chemistry)	X[b,c]	X[c]	X[c]
Clinical Chemistry (Other Biomarkers – Acute Phase Proteins)/Serum[d]	X[b,c]	X[c]	X[c]
Urinalysis	NA	X	X

NA = Not applicable; X = Scheduled collection.
a. First 7 animals/sex/group.
b. Last 8 animals/sex/group.
c. Blood samples were collected from animals in a fasted state, with the exception of same day redraws.
d. Assay performed using shared clinical chemistry sample.
e. Evaluated on animals scheduled for necropsy.

See the Clinical Pathology Report in Appendix B for complete materials and methods.

5.6.3. Antibody (Serology) Response to Vaccine Components

Sample Collection and Storage Conditions	
Groups:	1-3
Collection Intervals:	PID Phase Day 8 and Dosing Phase Day 17[a], and Recovery Phase Day 21[a]
Collection Time Points:	PID Phase Day 8, Dosing Phase Day 17, and Recovery Phase Day 21: Once
Animals/Time Point:	All animals
Anticoagulant:	No anticoagulant
Collection Volume per Sample:	PID Phase Day 8: Approximately 0.7 mL Dosing Phase Day 17 and Recovery Phase Day 21: Approximately 1 mL
Sample Processing:	Samples were processed and stored as appropriate within 2 hours of collection
Sample Storage Conditions:	Approximately -60°C or lower

PID = Prior to initiation of dosing.
a. Samples collected prior to necropsy.

All samples collected were sent in one shipment after completion of the last blood sample collection.

Antibody Analysis	
Analysis of Samples from Control Animals (Group 1):	All samples were analyzed
Analysis of Samples from Animals Administered Test Article:	All samples were analyzed for a neutralizing antibody response to the antigens in BNT162b2 (V9) and BNT162b3c

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Incurred Sample Reanalysis (ISR)/Project Numbers	
Antibody (Serology) Sample Analysis was conducted under the following Qualified Method ID:	PFZ_20GR142-WO4_MN SarsCov2_V2_20200924_GL

See the Serology Report in Appendix B for complete materials and methods.

5.7. Postmortem Observations

Animals (10/sex/group) were euthanized on Dosing Phase Day 17 (2 days after the last dose). Remaining animals were euthanized on Recovery Phase Day 22, the last day of the Recovery Phase (surviving animals).

Necropsy, tissue collection, organ weights, macroscopic tissue evaluation, and microscopic examination were performed.

Bone marrow smears were collected from all animals.

See the Anatomic Pathology Report in Appendix B for complete materials and methods.

5.8. Statistical Analysis

Statistical analyses of body weight, body weight change, and food consumption data were conducted in Pristima and analyses of body temperature and injection site scores were conducted by DSRD Statistics using iStats v1.0 with the methods outlined below. All analyses were performed separately for each sex.

Descriptive statistics were generated for each parameter and group at each scheduled sampling time or each time interval. Statistical tests were conducted at the 5% and 1% significance levels.

Analyses of body weight and food consumption parameters were done on measurements collected for each animal at the scheduled sampling times or time intervals. In addition, body weight change at selected intervals was analyzed. Analysis of body temperature was based on the maximum body temperature after injection for each animal. Analysis of injection site score was based on the average irritation score after injection for each animal.

A nonparametric (rank-transform) one way analysis of variance (ANOVA) on all groups was conducted, with two-sided pairwise comparisons of Groups 2 and 3 to Group 1 using Dunnett's test. Average ranks were assigned to ties.

For statistical analysis performed for contributing scientist activities/measurements, see the corresponding report in Appendix B.

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5.9. Data Acquisition

The following primary computer applications were used for the collection of data.

Computer Application	Data Collected/Usage
Pristima Preclinical Data Management Suite (Version 7.4.3)	In-life activities
DVMAX Research Version 3.1.2	Animal health records
Microsoft Excel	Sample tracking and antibody immunoassay result storage. Duplicate titration for each sample, provided two neutralization titers (MNt) for each sample. Information was documented according to VisMederi, Srl Standard Operating Procedures (WI-MNSARS-CoV-2) are stored in an Excel sheet (the basic format is provided in dedicated VisMederi, Srl procedure).
iStats Version 1.0	Statistical analysis

For data acquisition systems and version numbers of each of these systems used for contributing scientist/principal investigator activities/measurements, see the corresponding report in Appendix B.

5.10. Data Management and Archives

Data	Location of Archive
Raw data, documentation, protocol and amendments, final report, and any specimens generated at the Test Facility	Pfizer, Groton, CT
Raw data and documents electronically archived	Pfizer OpenLab archive system or locked and retained in the source computerized system, as defined as per SOP.
Materials are retained in accordance with the Enterprise Records Retention Schedule.	
Raw data, working sheets and any template required by method procedure are archived as hard copies (original documents) in fireproof archives up to 25 years. Electronic format outputs are regularly backed up and archived in Microsoft cloud.	

6. RESULTS

6.1. Clinical Observations/Measurements

6.1.1. Mortality

Individual animal mortality data are included in Appendix 1.

There was no unscheduled euthanasia. All animals administered BNT162b2 (V9) or BNT162b3c survived to scheduled necropsy at the end of the dosing or recovery phase of the study.

6.1.2. Clinical Signs

An incidence summary of clinical signs is presented in Table 1. Individual animal clinical signs are included in Appendix 2.

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There were no test article-related clinical signs noted for animals administered BNT162b2 (V9) or BNT162b3c during the dosing or recovery phase.

6.1.3. Body Weight

Group mean body weight data are presented in Table 3. Group mean body weight change during interval data are presented in Table 4. Individual animal body weight data are included in Appendix 4. Individual animal body weight change during interval data are included in Appendix 5.

Dosing Phase

No test article-related mean body weight changes were noted for animals administered BNT162b2 (V9) during the dosing phase.

Test article-related lower mean body weight (0.93x-0.94x control) was noted in males only on Days 11 and 15 for BNT162b3c during the dosing phase.

Recovery Phase

Test article-related higher mean body weight (1.05-1.06x control) was noted in males only on Recovery Days 11, 15, 18 and 21 for animals administered BNT162b2 (V9).

No test article related body weight changes were noted for animals administered BNT162b3c during the recovery phase.

Other differences between test article and control group were not test article-related due to the small magnitude of the change, inconsistent direction of the difference, and/or inconsistency of the response.

6.1.4. Food Consumption

Group mean food consumption data are presented in Table 5. Individual animal food consumption data are included in Appendix 6.

Dosing Phase

Test article-related lower mean food consumption (0.83x-0.87x control) was noted on Days 4 and 11 for animals administered BNT162b2 (V9) during the dosing phase.

Test article-related lower mean food consumption (0.76x-0.92x control) was noted on Days 4 and 11 for animals administered BNT162b3c during the dosing phase.

Recovery Phase

Test article-related higher mean food consumption (1.08x-1.35x control) was noted throughout the recovery phase for male animals administered BNT162b2 (V9).

Test article-related higher mean food consumption (1.08x-1.30x control) was noted on Recovery Phase Days 4 and 11 for male animals administered BNT162b3c.

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Other differences between test article and control group were not test article-related due to the small magnitude of the change, inconsistent direction of the difference, and/or inconsistency of the response.

6.1.5. Dermal Assessment

Group mean dermal assessment data are included in Table 12. Individual dermal assessment data are included in Appendix 12.

Dosing Phase

BNT162b2 (V9)-related injection site edema Grade 2 (slight, edges of area well defined by definite raising) or Grade 3 (moderate, raised approximately 1 mm) were noted in all animals (except Animal 17), and occurred following dosing on Days 1, 8 and/or 15 (see Text Table 1). The edema was generally observed up to 72 hours postdose, and fully resolved prior to dose administration on Days 8 and 15. Erythema was also observed at the injection site in all animals (except Animals 16-21 and 30), following each dose administration, however, it was only a Grade 1 (very slight, barely perceptible) and fully resolved prior to the next dose administration.

BNT162b3c-related injection site edema Grade 2 (slight, edges of area well defined by definite raising) or Grade 3 (moderate, raised approximately 1 mm) were noted in all animals, and occurred following dosing on Days 1, 8 and/or 15 (see Text Table 2). The edema was generally observed up to 72 hours postdose, and fully resolved prior to dose administration on Days 8 and 15. Erythema was also observed at the injection site in all animals (except Animal 39), following each dose administration, however, it was only a Grade 1 (very slight, barely perceptible) and fully resolved prior to the next dose administration.

Text Table 1. BNT162b2 (V9) Animals with Injection Site Edema Score ≥ 2

Animal	Clinical Sign	Total Number of Days (Dosing Phase Study Day of Occurrence)
16 M	Edema, Grade 2	1 (D16: 24 HPD)
18 M	Edema, Grade 2	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
19 M	Edema, Grade 2	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
20 M	Edema, Grade 2	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
21 M	Edema, Grade 2	6 (D2: 24 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
22 M	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
23 M	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
24 M	Edema, Grade 2	3 (D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
25 M	Edema, Grade 2	3 (D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)

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Text Table 1. BNT162b2 (V9) Animals with Injection Site Edema Score ≥ 2 - Cont'd

Animal	Clinical Sign	Total Number of Days (Dosing Phase Study Day of Occurrence)
26 M	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
27 M	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD)
	Edema, Grade 3	2 (D16: 24 HPD; D17: 48 HPD)
28 M	Edema, Grade 2	3 (D2: 24 HPD; D3: 48 HPD; D11: 72 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
29 M	Edema, Grade 2	1 (D11: 72 HPD)
	Edema, Grade 3	2 (D 9: 24 HPD; D10: 48 HPD)
30 M	Edema, Grade 2	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
61 F	Edema, Grade 2	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
62 F	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD)
	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
63 F	Edema, Grade 2	8 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD)
	Edema, Grade 3	2 (D16: 24 HPD; D17: 48 HPD)
64 F	Edema, Grade 2	9 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D17: 48 HPD)
	Edema, Grade 3	1 (D16: 24 HPD)
65 F	Edema, Grade 2	2 (D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	3 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD)
66 F	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D11: 72 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
67 F	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120, D7: 144; D17: 48 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD)
68 F	Edema, Grade 2	2 (D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	3 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD)
69 F	Edema, Grade 2	8 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD; D10: 48 HPD; D17: 48 HPD)
	Edema, Grade 3	1 (D16: 24 HPD)
70 F	Edema, Grade 2	2 (D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	3 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD)
71 F	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
72 F	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D11: 72 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
73 F	Edema, Grade 2	10 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
74 F	Edema, Grade 2	7 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D11: 72 HPD; D16: 24 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)

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Text Table 1. BNT162b2 (V9) Animals with Injection Site Edema Score ≥ 2 - Cont'd

Animal	Clinical Sign	Total Number of Days (Dosing Phase Study Day of Occurrence)
75 F	Edema, Grade 2	8 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD)
	Edema, Grade 3	2 (D16: 24 HPD; D17: 48 HPD)

Note: Dosing Days = 1, 8, and 15.
D = Dosing Phase Day; F = Female; HPD = Hours postdose M = Male.
Grade 0 = No edema; 1 = Very slight edema (barely perceptible); 2 = Slight edema (edges of area well defined by definite raising); 3 = Moderate edema (raised approximately 1 millimeter); 4 = Severe edema (raised more than 1 millimeter and extends beyond the area of exposure).

Text Table 2. BNT162b3c Animals with Injection Site Edema Score ≥ 2

Animal	Clinical Sign	Total Number of Days (Dosing Phase Study Day of Occurrence)
31 M	Edema, Grade 2	4 (D2: 24 HPD; D3: 48 HPD; D11: 72 HPD; D16: 24 HPD)
	Edema, Grade 3	3 (D9: 24 HPD; D10: 48 HPD; D17: 48 HPD)
32 M	Edema, Grade 2	2 (D9: 24 HPD; D10: 48 HPD)
33 M	Edema, Grade 2	3 (D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD: D10: 48 HPD)
34 M	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D9: 24 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	1 (D10: 48 HPD)
35 M	Edema, Grade 2	3 (D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
36 M	Edema, Grade 2	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
37 M	Edema, Grade 2	7 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
38 M	Edema, Grade 2	3 (D11; 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10:48 HPD)
39 M	Edema, Grade 2	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
40 M	Edema, Grade 2	3 (D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D 9: 24 HPD; D10: 48 HPD)
41 M	Edema, Grade 2	1 (D11: 72 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
42 M	Edema, Grade 2	3 (D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD; D10: 48 HPD)
43 M	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D11:72 HPD)
	Edema, Grade 3	4 (D 9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
44 M	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D11: 72 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
45 M	Edema, Grade 2	7 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
	Edema, Grade 3	2 (D9: 24 HPD: D10: 48 HPD)
76 F	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
77 F	Edema, Grade 2	1 (D13: 120 HPD)

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Text Table 2. BNT162b3c Animals with Injection Site Edema Score ≥ 2 - Cont'd

Animal	Clinical Sign	Total Number of Days (Dosing Phase Study Day of Occurrence)
	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
78 F	Edema, Grade 2	1 (D13: 120 HPD)
	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
79 F	Edema, Grade 2	7 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D11: 72 HPD; D17: 48 HPD)
	Edema, Grade 3	3 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD;)
80 F	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D11: 72 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
81 F	Edema, Grade 2	2 (D9: 24 HPD; D11: 72 HPD)
	Edema, Grade 3	3 (D10: 48 HPD; D16: 24 HPD; D17: 48 HPD)
82 F	Edema, Grade 2	2 (D11: 72 HPD; D17: 48 HPD)
	Edema, Grade 3	3 (D9: 24 HPD; D10: 48 HPD; D16: 24 HPD)
83 F	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD;)
	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
84 F	Edema, Grade 2	9 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D17: 48 HPD)
	Edema, Grade 3	1 (D16: 24 HPD)
85 F	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D16: 24 HPD)
	Edema, Grade 3	4 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D17: 48 HPD)
86 F	Edema, Grade 2	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
87 F	Edema, Grade 2	5 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD;)
	Edema, Grade 3	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
88 F	Edema, Grade 2	6 (D2: 24 HPD; D3: 48 HPD; D4: 72 HPD; D6: 120 HPD; D7: 144 HPD; D9: 24 HPD)
	Edema, Grade 3	4 (D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
89 F	Edema, Grade 2	5 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D16: 24 HPD; D17: 48 HPD)
90 F	Edema, Grade 2	6 (D9: 24 HPD; D10: 48 HPD; D11: 72 HPD; D13: 120 HPD; D16: 24 HPD; D17: 48 HPD)

Note: Doing Days = 1, 8, and 15.
D = Dosing Phase Day; F = Female; HPD = Hours postdose; M = Male.
Grade 0 = No edema; 1 = Very slight edema (barely perceptible); 2 = Slight edema (edges of area well defined by definite raising); 3 = Moderate edema (raised approximately 1 millimeter); 4 = Severe edema (raised more than 1 millimeter and extends beyond the area of exposure).

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Recovery Phase

BNT162b2 (V9)-related injection site edema Grade 2 (slight, edges of area well defined by definite raising) or Grade 3 (moderate, raised approximately 1 mm) was noted in 2/5 males and 5/5 females following dosing on Day 15 (see Text Table 3). The edema was generally observed up to 72 hours postdose, and fully resolved. Erythema was also observed at the injection site in 2/5 females after the final dose administration, however, it was only Grade 1 (very slight, barely perceptible) and fully resolved.

BNT162b3c -related injection site edema Grade 2 (slight, edges of area well defined by definite raising) or Grade 3 (moderate, raised approximately 1 mm) was noted in 4/5 males and 5/5 females following dosing on Day 15 (see Text Table 4). The edema was generally observed up to 72 hours postdose, and fully resolved. Erythema was also observed at the injection site in 4/5 females after the final dose administration, however, it was only Grade 1 (very slight, barely perceptible) and fully resolved.

Text Table 3. BNT162b2 (V9) Animals with Injection Site Edema Score ≥ 2

Animal	Clinical Sign	Total Number of Days (Recovery Study Day of Occurrence)
26 M	Edema, Grade 2	1 (RPD1; 72 HPD)
30 M	Edema, Grade 2	1 (RPD1; 72 HPD)
71 F	Edema, Grade 2	1 (RPD1; 72 HPD)
72 F	Edema, Grade 3	1 (RPD1; 72 HPD)
73 F	Edema, Grade 2	1 (RPD1; 72 HPD)
74 F	Edema, Grade 2	1 (RPD1; 72 HPD)
75 F	Edema, Grade 3	1 (RPD1; 72 HPD)

F = Female; HPD = Hours post dose; M = Male; RPD = Recovery Phase Day
Grade 0 = No edema; 1 = Very slight edema (barely perceptible); 2 = Slight edema (edges of area well defined by definite raising); 3 = Moderate edema (raised approximately 1 millimeter); 4 = Severe edema (raised more than 1 millimeter and extends beyond the area of exposure).

Text Table 4. BNT162b3c Animals with Injection Site Edema Score ≥ 2

Animal	Clinical Sign	Total Number of Days (Recovery Study Day of Occurrence)
41 M	Edema, Grade 2	1 (RPD1: 72 HPD)
43 M	Edema, Grade 2	1 (RPD1: 72 HPD)
44 M	Edema, Grade 2	1 (RPD1: 72 HPD)
45 M	Edema, Grade 2	1 (RPD1: 72 HPD)
86 F	Edema, Grade 2	1 (RPD1: 72 HPD)
87 F	Edema, Grade 3	1 (RPD1: 72 HPD)
88 F	Edema, Grade 3	1 (RPD1: 72 HPD)
89 F	Edema, Grade 3	1 (RPD1: 72 HPD)
90 F	Edema, Grade 2	1 (RPD1: 72 HPD)

F = Female; HPD = Hours post dose; M = Males; RPD = Recovery Phase Day.
Grade 0 = No edema; 1 = Very slight edema (barely perceptible); 2 = Slight edema (edges of area well defined by definite raising); 3 = Moderate edema (raised approximately 1 millimeter); 4 = Severe edema (raised more than 1 millimeter and extends beyond the area of exposure).

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6.1.6. Body Temperature

Group mean body temperature data are included in Table 13. Individual body temperature data are included in Appendix 13.

Test article-related higher mean body temperature differences from control were noted on Days 1 (+0.42°C-0.54°C), 8 (+0.66°C-0.98°C), and 15 (+0.13°C-1.03°C) following dose administration of BNT162b2 (V9).

Test article-related higher mean body temperature differences from control were noted on Days 1 (+0.50°C-0.71°C), 8 (+0.92°C-1.26°C) and 15 (+0.33°C-1.09°C) following dose administration of BNT162b3c.

Additional body temperature evaluations were not needed at 48 and 72 hours postdose as individual animal body temperatures were ≤40°C at 24 hours postdose.

6.1.7. Ophthalmology

The complete Ophthalmology Report is included in Appendix B and a summary of the results is included below.

There were no test article-related ophthalmic findings noted at the conclusion of the dosing phase. Recovery phase examinations were not performed due to no findings observed at the conclusion of the dosing phase.

6.2. Clinical Laboratory Measurements

The complete Clinical Pathology Report is included in Appendix B and a summary of the results is included below.

Dosing Phase

Test article-related hematology and coagulation findings were similar in rats administered either BNT162b2(V9) or BNT162b3c and included higher mean white blood cell (WBC) counts and fibrinogen concentrations, lower (Day 4) and higher (Day 17) reticulocyte counts, and lower red blood cell mass (red blood cell count, hemoglobin and hematocrit) as compared with controls.

Higher WBC primarily involved higher neutrophils, monocytes and large unstained cells , but also eosinophils and basophils. They were present on Days 4 and 17, with higher counts on Day 17 than Day 4. On Day 17, there were also test article-related higher fibrinogen concentrations in both sexes. Hypersegmented neutrophils were present on peripheral blood smears of test article-dosed animals.

In addition, there were test article-related transiently lower reticulocyte counts on Day 4, and higher reticulocytes on Day 17 (females only) with attendant expected changes in RBC indices (higher mean cell hemoglobin concentration; males on Day 4; lower mean cell hemoglobin [MCH] and higher red cell distribution width on Day 17; both sexes). These

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were associated with lower RBC mass on Days 4 and 17 (comparable on both days or slightly lower on Day 17).

Test article-related clinical chemistry findings were similar in rats administered either BNT162b2(V9) or BNT162b3c and included higher mean alpha-1 acid glycoprotein and alpha-2-macroglobulin and lower AG ratios (primarily due to lower albumin with slight contribution from higher globulins) on Days 4 and 17 in both sexes.

Recovery Phase

All test article-related hematology and coagulation changes noted in the dosing phase were fully reversed after a 3-week recovery phase, with the exception of higher red cell distribution width.

All test article-related clinical chemistry changes noted in the dosing phase were fully reversed after a 3-week recovery phase, with the exception of higher globulins in males administered BNT162b2(V9) and females administered BNT162b2(V9) and BNT162b3c and lower AG ratio in females administered BNT162b2(V9).

There were no test article-related findings noted in urinalysis parameters in the dosing or recovery phase.

6.2.1. Bone Marrow Assessment

The complete Clinical Pathology Report is included in Appendix B and a summary of the results is included below.

Bone marrow smears were prepared for all animals and were not examined.

6.3. Antibody (Serology) Analysis

The complete Serology Report is included in Appendix B and a summary of the results is included below.

Administration of 3 once weekly doses of BNT162b2 (V9) or BNT162b3c elicited SARS-CoV-2 neutralizing antibody responses in males and females at the end of the dosing (Day 17) and recovery phases (Day 21) of the study. SARS-CoV-2 neutralizing antibody responses were not observed in animals prior to vaccine administration or in saline-administered control animals.

6.4. Postmortem Observations

The complete Anatomic Pathology Report is included in Appendix B and a summary of the results is included below.

Dosing Phase

Test article-related organ weight differences included higher absolute and relative (to body and brain weight) spleen weights in males and females administered BNT162b2 (V9) or BNT162b3c.

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Test article-related macroscopic findings included large draining lymph nodes (abnormal size, enlarged) and dark/pale and/or firm injection sites (abnormal color, dark/pale and/or abnormal consistency, firm) in animals administered BNT162b2 (V9) or BNT162b3c, and large spleen and inguinal lymph nodes (abnormal size, enlarged) in animals administered BNT162b3c.

Organs with test article-related microscopic findings included the injection site (mixed cell inflammation and edema), draining and inguinal lymph nodes (increased cellularity, plasma cells and germinal centers), liver (hepatocellular vacuolation), spleen (increased cellularity, hematopoietic cells and germinal centers), and bone marrow (increased cellularity, hematopoietic cells) in both males and females administered BNT162b2 (V9) or BNT162b3c.

Recovery Phase

No test article-related organ weight changes were noted at the end of the recovery phase.

Test article-related macroscopic findings observed at the end of the recovery phase were limited to large draining lymph nodes (abnormal size, enlarged) in 1 male administered BNT162b2 (V9) and 1 female administered BNT162b3c and large inguinal lymph nodes (abnormal size, enlarged) in 1 female administered BNT162b3c, indicating a partial recovery of these findings. Pale/dark and/or firm injection sites and enlarged spleen were not observed at the end of recovery phase in BNT162b2 (V9) or BNT162b3c administered males and females, indicating a complete recovery of these findings.

Test article-related microscopic findings noted at the end of the dosing phase including edema at the injection site, hepatocellular vacuolation in the liver, and increased cellularity of hematopoietic cells in the spleen and bone marrow were not observed at the end of recovery phase in BNT162b2 (V9) or BNT162b3c administered males and females, indicating a complete recovery of these findings. Inflammation at the injection site was characterized by mostly lymphocytes and plasma cells with few neutrophils (indicating partial recovery) and no edema (full recovery). However, increased cellularity of the germinal centers in the spleen partially recovered, as the incidence and/or severity of these findings were lower in recovery phase animals as compared with dosing phase animals in both males and females administered BNT162b2 (V9) or BNT162b3c. At the end of recovery phase, mature plasma cells had replaced the plasmablasts identified in the inguinal and draining lymph nodes in the dosing phase animals. In recovery phase animals, infiltration of macrophages was observed in the draining lymph nodes (minimal to mild) in both sexes administered BNT162b2 (V9) or BNT162b3c and in the inguinal lymph nodes (minimal) in both sexes administered BNT162b2 (V9). This finding was considered indicative of a reparative process (consequence of phagocytosis), which can be seen following inflammatory reactions at the injection sites.

7. INTEGRATED SUMMARY AND DISCUSSION OF RESULTS

Intramuscular administration of BNT162b2 (V9) and BNT162b3c at 30 µg RNA/dose day once weekly for a total of 3 doses to Wistar Han rats was tolerated during the dosing phase without evidence of systemic toxicity, generated a SARS-CoV-2 neutralizing antibody

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response, and produced nonadverse changes consistent with inflammatory and immune responses to vaccine administration.

At the conclusion of the dosing phase, test article-related responses to both vaccines were evident as transient edema (very slight to moderate) and erythema (very slight) at the injection site after each dose of BNT162b2 (V9) and BNT162b3c. Test article-related erythema and edema fully resolved prior to subsequent dose administration on Days 8 and 15 with findings generally resolved by 72 hours after the final dose administration (Recovery Phase Day 1). Transiently higher body temperature differences compared with concurrent controls were noted on Days 1 (up to +0.71°C), 8 (up to +1.26°C) and 15 (up to +1.09°C) post administration of BNT162b3c and on Days 1 (up to +0.54°C), 8 (up to +0.98°C), and 15 (up to +1.03°C) after administration of BNT162b2 (V9). Additional body temperature evaluations were not needed at 48 and 72 hours postdose as individual animal body temperatures were ≤40°C at 24 hours postdose.

Changes secondary to inflammation included lower mean body weight (0.93x-0.94x control on Days 11 and 15) in male animals administered BNT162b3c and lower mean food consumption (0.83x-0.87x control on Days 4 and 11) for animals administered BNT162b2 (V9) and BNT162b3c (0.76x-0.92x control on Days 4 and 11) during the dosing phase. These changes fully resolved in the recovery phase as higher mean body weight (1.05-1.06x control) was noted in males only administered BNT162b2 (V9). Additionally, higher mean food consumption (1.08x-1.35x control) was noted throughout the recovery phase for male animals administered BNT162b2 (V9) and BNT162b3c (1.08x-1.30x control).

At the conclusion of the dosing phase, all clinical pathology findings (type and magnitude) were generally similar between rats administered BNT162b2 (V9) or BNT162b3c, and consistent with expected immune responses to vaccines or secondary to inflammation. The main findings were present in both sexes on Days 4 and/or 17 and included higher acute phase proteins (alpha-1 acid glycoprotein; 7.0x-42x controls], alpha-2-macroglobulin (3.3x-128x] and fibrinogen [2.4x-2.6x]) and white blood cell count (1.28x-2.95x; primarily involving neutrophils, monocytes and large unstained cells, which typically represent large mononuclear cells) and lower albumin:globulin (0.90x-0.82x). Hypersegmented neutrophils present on peripheral blood smears were considered to be secondary to the robust increases in neutrophil counts and likely related to mobilization of bone marrow storage neutrophils and prolonged neutrophil lifespan in circulation (Ulich et al, 1988). Collectively, these findings were consistent with immune responses to vaccines. Microscopic correlates included minimally increased cellularity of hematopoietic cells (primarily myeloid) in the bone marrow and the spleen, minimal to moderate mixed cell inflammation at the injection site and increased cellularity in germinal centers of lymphoid organs. In addition, there were transiently lower reticulocyte counts on Day 4 (0.44x-0.27x), and higher reticulocytes on Day 17 (1.20x-1.31x; females only), with minor lower red cell mass on Days 4 and 17 (HCT; 0.93x-0.89x). Lower reticulocytes were interpreted to be a transient effect of innate immune responses (Abreu et al, 2018; Brooks et al, 2017; Kim et al, 2014; Wrighting & Andrews, 2006).

All test article-related clinical pathology parameter changes were fully reversed after a 3-week recovery phase, with the exception of higher red cell distribution width in males and

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females administered BNT162b2(V9) (1.13x and 1.21x, respectively) and BNT162b3c (1.12x and 1.23x, respectively), higher globulins in males administered BNT162b2(V9) (1.08x) and females administered BNT162b2(V9) (1.06x) and BNT162b3c (1.07x) and lower AG ratio in females administered BNT162b2(V9) (0.91x).

Test article-related microscopic pathology findings were observed at the injection site and in the lymph nodes, spleen, bone marrow, and liver for both vaccine candidates. All microscopic findings were nonadverse, as there was no evidence of systemic toxicity or clinical signs of illness or lameness.

At the end of the dosing phase, test article-related mixed cell inflammation (mild to moderate) and edema (mild to moderate) at the injection site were consistent with findings typically associated with the IM administration of lipid nanoparticle (LNP)-encapsulated mRNA vaccines (Hassett et al, 2019). These findings correlated with macroscopic observations of abnormal color (dark/pale) and consistency (firm). At the end of the 3-week recovery phase, full recovery occurred for macroscopic findings of pale/dark and firm injection sites and the microscopic finding of edema, whereas partial recovery occurred for inflammation at the injection sites.

At the end of the dosing phase, test article-related findings in the lymph nodes (increased cellularity of plasma cells [minimal to moderate] and germinal centers [minimal to mild]), spleen (increased cellularity of hematopoietic cells [minimal] and germinal centers [minimal]), and the bone marrow (minimal increased cellularity of hematopoietic cells) were secondary to immune activation and/or inflammation at the injection site. The presence of plasma cells (interpreted as plasmablasts) in the draining and inguinal lymph nodes was interpreted to reflect a robust immunological response to the vaccines. These observations correlated with macroscopic observations of abnormal size (enlarged) in the lymph nodes and spleen and increased spleen weights. At the end of the 3-week recovery phase, full recovery occurred for higher spleen weights, macroscopic finding of enlarged spleen, and microscopic findings of increased cellularity of hematopoietic cells in the spleen and bone marrow, whereas partial recovery occurred for macroscopic findings of enlarged draining and inguinal lymph nodes, microscopic findings of increased cellularity of plasma cells and germinal centers in the draining and inguinal lymph nodes, and increased cellularity of the germinal centers in the spleen.

At the end of the dosing phase, test article-related microscopic finding of minimal portal hepatocyte vacuolation was not associated with hepatic tissue damage or liver enzyme alterations. This change may be related to hepatic clearance of the pegylated lipid in the LNP (Ivens et al, 2015). At the end of 3-week recovery phase, this finding was completely recovered.

Administration of 3 once weekly doses of BNT162b2 (V9) or BNT162b3c elicited SARS-CoV-2 neutralizing antibody responses in both males and females at the end of the dosing (Day 17) and recovery phases (Day 21) of the study. SARS-CoV-2 neutralizing antibody responses were not observed in animals prior to vaccine administration or in saline-administered control animals.

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There were no other test article-related effects in the study.

8. CONCLUSIONS

In conclusion, BNT162b2 (V9) and BNT162b3c administered via intramuscular injection once weekly for a total of 3 doses to Wistar Han (Crl:WI[Han]) rats was tolerated without evidence of systemic toxicity, generated a SARS-CoV-2 neutralizing antibody response, and produced nonadverse changes consistent with an immune or inflammatory response at the conclusion of the dosing phase. At the end of the 3-week recovery phase, full or partial recovery of all findings was observed. Other nonadverse findings included vacuolation in the liver which may be related to hepatic clearance of PEGylated lipids and was noted at the conclusion of the dosing phase and completely recovered. The findings in this study are consistent with those typically associated with the intramuscular administration of LNP-encapsulated mRNA vaccines. Animals administered BNT162b2 (V9) or BNT162b3c elicited SARS-CoV-2 neutralizing antibody responses at the end of the dosing and recovery phases of the study.

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Table 1

Clinical Signs - Daily Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Animals were considered normal (data not displayed in table) unless indicated otherwise.

PID = Prior to Initiation of Dosing

- = Value not applicable.

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Table 1

Clinical Signs - Daily Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Males (PID)

Group Number:	1		2		3	
Dose:	0 µg/day		30 µg/day		30 µg /day	
Number of animals:	15		15		15	
Number Examined:	15		15		15	
Number Normal:	15		14		15	
Observations	a	b	a	b	a	b
Tail Crooked	0	0	1	12	0	0

Note: a = Number of animals with Observation
b = Number of days Observation seen

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Table 1

Clinical Signs - Daily Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Males (Dosing)

Group Number:	1		2		3	
Dose:	0 µg/day		30 µg/day		30 µg /day	
Number of animals:	15		15		15	
Number Examined:	15		15		15	
Number Normal:	14		13		15	
Observations	a	b	a	b	a	b
Tail Crooked	0	0	1	17	0	0
Thin Appearance	1	1	0	0	0	0
Hair Loss	0	0	1	2	0	0

Note: a = Number of animals with Observation
b = Number of days Observation seen

Table 1

Clinical Signs - Daily Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Males (Recovery)

Group Number:	1		2		3	
Dose:	0 µg/day		30 µg/day		30 µg /day	
Number of animals:	15		15		15	
Number Examined:	5		5		5	
Number Normal:	5		4		5	
Observations	a	b	a	b	a	b
Tail Crooked	0	0	1	22	0	0

Note: a = Number of animals with Observation
b = Number of days Observation seen

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Table 1

Clinical Signs - Daily Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Females (Dosing)

Group Number:	1		2		3	
Dose:	0 µg/day		30 µg/day		30 µg /day	
Number of animals:	15		15		15	
Number Examined:	15		15		15	
Number Normal:	15		14		14	
Observations	a	b	a	b	a	b
Lesion	0	0	0	0	1	1
Hair Loss	0	0	1	1	0	0

Note: a = Number of animals with Observation
b = Number of days Observation seen

Table 2

Ocular Exam Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Animals were considered normal (data not displayed in table) unless indicated otherwise.

PID = Prior to Initiation of Dosing

- = Value not applicable.

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Table 2

Ocular Exam Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Males (PID)

	Group Number:	1		2		3	
	Dose:	0 µg/day		30 µg/day		30 µg /day	
	Number of animals:	15		15		15	
	Number Examined:	15		15		15	
	Number Normal:	0		0		0	
Observations		a	b	a	b	a	b
Keratic Precipitates		1	1	0	0	1	1
No Ocular Abnormality		11	1	15	1	14	1
Retina, Tortuous Vessels		1	1	0	0	0	0
Vitreous, Hemorrhage		1	1	0	0	0	0
Vitreous, Hyaloid Remnant		1	1	0	0	0	0

Note: a = Number of animals with Observation
b = Number of days Observation seen

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Table 2

Ocular Exam Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Males (Dosing)

Group Number:	1		2		3	
Dose:	0 µg/day		30 µg/day		30 µg /day	
Number of animals:	15		15		15	
Number Examined:	15		15		15	
Number Normal:	0		0		0	
Observations	a	b	a	b	a	b
Keratic Precipitates	1	1	0	0	1	1
No Ocular Abnormality	11	1	15	1	14	1
Retina, Tortuous Vessels	1	1	0	0	0	0
Vitreous, Hemorrhage	1	1	0	0	0	0
Vitreous, Hyaloid Remnant	1	1	0	0	0	0

Note: a = Number of animals with Observation
b = Number of days Observation seen

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Table 2

Ocular Exam Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Females (PID)

Group Number:	1		2		3			
Dose:	0 µg/day		30 µg/day		30 µg /day			
Number of animals:	15		15		15			
Number Examined:	15		15		15			
Number Normal:	0		0		0			
Observations	a	b	a	b	a	b		
No Ocular Abnormality	15	1	15	1	15	2		

Note: a = Number of animals with Observation
b = Number of days Observation seen

Table 2

Ocular Exam Summary Report by Interval

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Females (Dosing)

Group Number:	1		2		3	
Dose:	0 µg/day		30 µg/day		30 µg /day	
Number of animals:	15		15		15	
Number Examined:	15		15		15	
Number Normal:	0		0		0	
Observations	a	b	a	b	a	b
Keratic Precipitates	1	1	0	0	0	0
No Ocular Abnormality	14	1	15	1	15	1

Note: a = Number of animals with Observation
b = Number of days Observation seen

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Table 3

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

N = Sample Size; SD = Standard Deviation; - = Value not applicable;
@ = Number examined reduced due to excluded data; e = Group mean excluded from statistics;
REF = Denotes group used as reference in the statistical tests;
* = Statistically significant pairwise comparison at 0.05 level;
† = Statistically significant pairwise comparison at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level.
+ = Ascending trend sign;
- = Descending trend sign;

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Table 3

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

	Group Number:		REF		2			3			
	Dose:		0 µg/day		30 µg/day			30 µg /day			
Phase	**Day**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	
PID	1	15	187.71	8.56	15	188.41	7.75	15	188.03	6.62	
	6	15	225.28	9.66	15	226.59	8.47	15	225.85	8.67	
Dosing	1	15	264.80	11.89	15	267.18	8.15	15	263.46	12.10	
	4	15	252.16	10.99	15	247.61	10.02	15	242.54	13.20	
	8	15	280.60	25.91	15	283.61	12.16	15	276.29	15.86	
	11	15	295.83	17.57	15	283.71	13.88	15	274.58	18.39	†
	15	15	311.47	17.82	15	302.53	15.32	15	293.29	17.38	*
Recovery	1	5	307.70	21.74	5	308.50	12.01	5	295.92	9.49	
	4	5	316.08	25.11	5	320.72	13.14	5	306.16	9.09	
	8	5	326.54	29.34	5	332.88	15.20	5	320.72	10.07	
	11	5	330.74	30.51	5	346.54	14.64	5	327.60	8.95	
	15	5	333.60	32.63	5	354.64	18.28	5	334.80	12.51	
	18	5	341.42	35.91	5	359.48	16.87	5	344.14	12.32	
	21	5	347.88	39.32	5	369.60	21.74	5	354.24	11.39	

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Table 3

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

	Group Number:		REF			2			3	
	Dose:		0 µg/day			30 µg/day			30 µg /day	
Phase	**Day**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
PID	1	15	158.37	7.52	15	159.83	7.42	15	159.57	6.72
	6	15	176.36	7.52	15	176.31	7.51	15	175.61	9.68
Dosing	1	15	194.79	8.63	15	191.53	8.38	15	192.68	9.71
	4	15	183.19	8.90	15	177.31	6.25	15	176.93	7.46
	8	15	206.53	11.91	15	202.51	7.98	15	198.91	12.14
	11	15	210.23	12.88	15	203.88	8.25	15	202.83	11.29
	15	15	214.29	11.95	15	214.02	11.69	15	213.93	14.12
Recovery	1	5	215.08	14.40	5	207.22	4.75	5	211.92	22.04
	4	5	217.14	16.97	5	213.00	7.23	5	214.38	17.62
	8	5	224.02	20.44	5	220.14	7.28	5	219.88	17.62
	11	5	224.02	17.73	5	221.50	7.28	5	218.22	15.76
	15	5	224.24	13.98	5	220.58	5.81	5	217.30	19.01
	18	5	225.54	15.89	5	224.56	7.07	5	225.18	20.90
	21	5	228.86	14.34	5	231.32	10.43	5	224.46	18.18

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Table 4

Body Weight Change During Interval (g)
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

N = Sample Size; SD = Standard Deviation; - = Value not applicable;
@= Number examined reduced due to excluded data; e= Group mean excluded from statistics;
REF = Denotes group used as reference in the statistical tests;
* = Statistically significant pairwise comparison at 0.05 level;
† = Statistically significant pairwise comparison at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level;
+ = Ascending trend sign;
- = Descending trend sign;

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Document 2

Table 4

Body Weight Change During Interval (g)
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

	Group Number:		REF			2			3	
	Dose:		0 µg/day			30 µg/day			30 µg /day	
Phase	**Days**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
PID	1-6	15	37.57	5.03	15	38.17	3.68	15	37.81	5.25
Dosing	1-4	15	-12.64	6.48	15	-19.57	4.15 †	15	-20.92	5.13 †
	4-8	15	28.44	20.74	15	36.01	5.43	15	33.75	6.25
	8-11	15	15.23	13.92	15	0.10	4.24 †	15	-1.71	4.92 †
	11-15	15	15.64	6.06	15	18.82	3.78 *	15	18.71	3.81
	1-15	15	46.67	11.76	15	35.35	9.13 †	15	29.83	7.68 †
Recovery	1-4	5	8.38	6.59	5	12.22	3.59	5	10.24	1.50
	4-8	5	10.46	5.99	5	12.16	3.36	5	14.56	2.43
	8-11	5	4.20	2.25	5	13.66	5.19 †	5	6.88	2.09
	11-15	5	2.86	5.01	5	8.10	4.39	5	7.20	4.36
	15-18	5	7.82	4.23	5	4.84	2.74	5	9.34	1.78
	18-21	5	6.46	3.71	5	10.12	5.61	5	10.10	4.17
	1-21	5	40.18	23.53	5	61.10	11.09	5	58.32	2.92

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Table 4

Body Weight Change During Interval (g)
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

	Group Number:		REF			2			3	
	Dose:		0 µg/day			30 µg/day			30 µg /day	
Phase	**Days**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
PID	1-6	15	17.99	2.73	15	16.48	4.42	15	16.03	5.51
Dosing	1-4	15	-11.61	4.28	15	-14.21	4.68	15	-15.75	4.41
	4-8	15	23.34	6.05	15	25.19	3.75	15	21.98	6.34
	8-11	15	3.71	6.72	15	1.37	5.88	15	3.92	6.86
	11-15	15	4.06	2.94	15	10.14	5.89 †	15	11.09	7.60 †
	1-15	15	19.50	10.28	15	22.49	7.98	15	21.25	9.62
Recovery	1-4	5	2.06	4.97	5	5.78	7.47	5	2.46	8.25
	4-8	5	6.88	5.44	5	7.14	3.16	5	5.50	2.38
	8-11	5	0.00	6.15	5	1.36	4.33	5	-1.66	4.65
	11-15	5	0.22	5.29	5	-0.92	3.88	5	-0.92	7.60
	15-18	5	1.30	3.45	5	3.98	3.54	5	7.88	2.12 †
	18-21	5	3.32	6.18	5	6.76	7.21	5	-0.72	6.12
	1-21	5	13.78	7.24	5	24.10	9.09	5	12.54	9.04

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Table 5

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

N = Sample Size; SD = Standard Deviation; -= Value not applicable;
@= Number examined reduced due to excluded data; e= Group mean excluded from statistics;
REF = Denotes group used as reference in the statistical tree;
* = Statistically significant pairwise comparison at 0.05 level;
† = Statistically significant pairwise comparison at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level;
+ = Ascending trend sign;
- = Descending trend sign;

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Table 5

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

	Group Number:		REF			2				3			
	Dose:		0 µg/day			30 µg/day				30 µg /day			
Phase	**Days**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**		**N**	**Mean**	**SD**		
Dosing	1-4	15	50.88	4.05	15	42.59	4.28	†	15	38.69	5.13	†	
	4-8	15	90.87	21.27	15	96.75	8.55		15	91.37	11.71		
	8-11	15	64.77	5.09	15	54.02	6.13	†	15	50.45	7.45	†	
	11-15	15	89.35	5.58	15	92.22	8.57		15	88.80	8.32		
	1-15	15	295.87	26.49	15	285.59	25.00		15	269.31	27.34	*	
Recovery	1-4	5	48.02	6.41	5	64.74	3.38	†	5	62.26	4.67	†	
	4-8	5	82.12	11.18	5	92.92	7.90		5	86.64	6.45		
	8-11	5	58.12	6.67	5	68.00	5.18	*	5	62.70	4.15		
	11-15	5	76.42	9.49	5	84.72	7.87		5	79.20	6.20		
	15-18	5	59.70	8.18	5	64.46	3.81		5	62.60	5.08		
	18-21	5	59.28	9.02	5	66.44	4.09		5	62.14	7.53		
	1-21	5	383.66	49.21	5	441.28	29.93		5	415.54	31.74		

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Table 5

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

	Group Number:		REF			2			3		
	Dose:		0 µg/day			30 µg/day			30 µg /day		
Phase	**Days**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**		**N**	**Mean**	**SD**	
Dosing	1-4	15	37.79	4.28	15	33.02	3.62	†	15	34.63	12.73	†
	4-8	15	74.46	8.29	15	70.83	4.58		15	71.73	6.76	
	8-11	15	48.27	6.64	15	41.85	2.97	†	15	40.42	6.17	†
	11-15	15	65.27	7.36	15	66.59	6.62		15	68.50	8.71	
	1-15	15	225.80	24.33	15	212.29	13.55		15	215.28	24.59	
Recovery	1-4	5	47.60	5.58	5	49.72	4.93		5	49.02	5.33	
	4-8	5	63.32	7.66	5	66.68	2.93		5	66.88	9.55	
	8-11	5	46.32	4.38	5	46.70	3.76		5	42.72	6.58	
	11-15	5	59.08	7.68	5	60.98	4.18		5	57.88	11.68	
	15-18	5	42.44	5.72	5	43.64	5.88		5	44.76	7.31	
	18-21	5	45.00	4.09	5	46.80	4.13		5	44.76	6.43	
	1-21	5	303.76	32.65	5	314.52	18.16		5	306.02	44.46	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description
RBC	Red Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Cell Volume
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Conc
RDW	Red Cell Distribution Width
RETIC	Reticulocyte, Absolute
PLT	Platelets
MPV	Mean Platelet Volume
WBC	White Blood Cells
NEUT	Neutrophil, Absolute
LYM	Lymphocyte, Absolute
MONO	Monocyte, Absolute
EO	Eosinophil, Absolute
BASO	Basophil, Absolute
LUC	Large Unstained Cells, Absolute
PT_Rat	Prothrombin Time, Rat
APTT	Activated Partial Thromboplastin Time
FIB	Fibrinogen

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Table 6

Hematology and Coagulation
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Sample size is displayed in ( ) before the mean value.
SD = Standard Deviation; - = Value not applicable;
Units are displayed in the ( ) under each parameter name;
HPD = Hours Post Dose; U = Unscheduled;
e = Group mean excluded from statistics;
REF = Denotes group used as reference in the statistical test;
* = Statistically significant pairwise comparison at 0.05 level;
† = Statistically significant pairwise comparison at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level.
+ = Ascending trend sign;
- = Descending trend sign;
= Individual parameter values reported as less than or greater than limit of quantitation are set equal to the limit to calculate the average.

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day		30 µg /day	
RBC (10^6/uL)	Dosing	4	--	Mean	(7) 8.117		(7) 7.774	*	(7) 7.596	†
				SD	0.265		0.292		0.273	
		17	-	Mean	(9) 7.584		(10) 7.169		(10) 7.113	
				SD	0.512		0.292		0.326	
	Recovery	22	-	Mean	(5) 7.950		(5) 8.064		(5) 7.886	
				SD	0.480		0.261		0.427	
HGB (g/dL)	Dosing	4	--	Mean	(7) 15.01		(7) 14.16	*	(7) 14.01	†
				SD	0.57		0.62		0.38	
		17	-	Mean	(9) 13.82		(10) 12.53	†	(10) 12.81	†
				SD	0.72		0.63		0.49	
	Recovery	22	-	Mean	(5) 14.36		(5) 14.38		(5) 14.00	
				SD	1.02		0.41		0.45	
HCT (%)	Dosing	4	--	Mean	(7) 48.04		(7) 43.37	†	(7) 43.79	†
				SD	1.33		1.69		1.16	
		17	-	Mean	(9) 42.61		(10) 38.40	†	(10) 39.29	*
				SD	2.44		1.64		1.49	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day		30 µg /day	
HCT (%)	Recovery	22	-	Mean	(5) 42.78		(5) 43.72		(5) 42.98	
				SD	3.12		1.44		2.00	
MCV (fL)	Dosing	4	--	Mean	(7) 59.19		(7) 55.81	†	(7) 57.69	
				SD	1.21		1.28		1.52	
		17	-	Mean	(9) 56.24		(10) 53.58	†	(9) 54.99	
				SD	1.37		1.36		1.35	
	Recovery	22	-	Mean	(4) 53.80		(4) 54.00		(4) 54.30	
				SD	1.15		1.03		1.25	
MCH (pg)	Dosing	4	--	Mean	(7) 18.51		(7) 18.20		(7) 18.50	
				SD	0.48		0.49		0.47	
		17	-	Mean	(9) 18.27		(10) 17.48	†	(10) 18.01	
				SD	0.42		0.51		0.60	
	Recovery	22	-	Mean	(5) 18.06		(5) 17.84		(5) 17.80	
				SD	0.43		0.64		0.66	
MCHC (g/dL)	Dosing	4	--	Mean	(7) 31.24		(7) 32.64	†	(7) 32.04	†
				SD	0.57		0.40		0.26	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
MCHC (g/dL)	Dosing	17	-	**Mean**	(9) 32.46		(10) 32.65		(10) 32.61	
				SD	0.36		0.53		0.64	
	Recovery	22	-	**Mean**	(5) 33.60		(5) 32.90		(5) 32.60	*
				SD	0.71		0.74		0.63	
RDW (%)	Dosing	4	--	**Mean**	(7) 12.27		(7) 12.83		(7) 12.44	
				SD	0.47		0.70		0.49	
		17	-	**Mean**	(9) 11.63		(10) 14.12	†	(9) 13.73	†
				SD	0.39		0.73		0.46	
	Recovery	22	-	**Mean**	(4) 11.93		(4) 13.48	†	(4) 13.33	*
				SD	0.42		0.29		0.46	
RETIC (10^3/uL)	Dosing	4	--	**Mean**	(7) 392.1		(7) 107.4	†	(7) 104.6	†
				SD	51.5		46.9		27.3	
		17	-	**Mean**	(9) 178.8		(10) 185.4		(10) 194.0	
				SD	24.1		25.9		12.4	
	Recovery	22	-	**Mean**	(5) 180.8		(5) 190.8		(5) 186.6	
				SD	28.9		30.4		25.4	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2			3		
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day			30 µg /day		
PLT (10^3/uL)	Dosing	4	--	Mean	(7)	1012.7	(7)	1039.7		(7)	945.1	
				SD		169.9		94.7			132.1	
		17	-	Mean	(9)	881.3	(10)	801.3		(10)	739.0	*
				SD		69.0		119.9			133.1	
	Recovery	22	-	Mean	(5)	847.8	(5)	904.4		(5)	837.6	
				SD		40.0		115.4			115.3	
MPV (fL)	Dosing	4	--	Mean	(7)	8.87	(7)	9.14		(7)	9.70	†
				SD		0.35		0.71			0.37	
		17	-	Mean	(9)	9.12	(10)	9.55		(10)	9.93	†
				SD		0.36		0.47			0.51	
	Recovery	22	-	Mean	(5)	9.00	(5)	8.84		(5)	8.88	
				SD		0.23		0.24			0.26	
WBC (10e3/uL)	Dosing	4	--	Mean	(7)	7.60	(7)	10.70	*	(7)	9.70	
				SD		1.08		3.01			1.64	
		17	-	Mean	(9)	3.84	(10)	8.83	†	(10)	8.60	†
				SD		1.67		3.62			1.15	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
WBC (10e3/uL)	Recovery	22	-	**Mean**	(5) 5.26		(5) 5.98		(5) 4.90	
				SD	2.64		1.16		1.18	
NEUT (10^3/uL)	Dosing	4	--	**Mean**	(7) 1.083		(7) 2.470	†	(7) 2.161	*
				SD	0.420		0.834		0.521	
		17	-	**Mean**	(9) 0.674		(10) 4.449	†	(10) 4.351	†
				SD	0.387		1.890		0.696	
	Recovery	22	-	**Mean**	(5) 0.898		(5) 1.070		(5) 1.276	
				SD	0.372		0.215		0.329	
LYM (10^3/uL)	Dosing	4	--	**Mean**	(7) 6.284		(7) 7.727		(7) 7.030	
				SD	1.048		2.157		1.150	
		17	-	**Mean**	(9) 3.009		(10) 3.792		(10) 3.547	
				SD	1.282		1.624		0.574	
	Recovery	22	-	**Mean**	(5) 4.158		(5) 4.672		(5) 3.408	
				SD	2.205		1.107		0.839	
MONO (10^3/uL)	Dosing	4	--	**Mean**	(7) 0.109		(7) 0.199	*	(7) 0.214	†
				SD	0.021		0.079		0.022	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day		30 µg /day	
MONO (10^3/uL)	Dosing	17	-	Mean	(9) 0.071		(10) 0.234	†	(10) 0.254	†
				SD	0.042		0.121		0.077	
	Recovery	22	-	Mean	(5) 0.074		(5) 0.106		(5) 0.104	
				SD	0.031		0.021		0.021	
EO (10^3/uL)	Dosing	4	--	Mean	(7) 0.081		(7) 0.086		(7) 0.091	
				SD	0.059		0.054		0.034	
		17	-	Mean	(9) 0.056		(10) 0.141	†	(10) 0.122	†
				SD	0.024		0.053		0.061	
	Recovery	22	-	Mean	(5) 0.068		(5) 0.074		(5) 0.074	
				SD	0.042		0.024		0.038	
BASO (10^3/uL)	Dosing	4	--	Mean	(7) 0.016		(7) 0.030	*	(7) 0.037	†
				SD	0.005		0.014		0.014	
		17	-	Mean	(9) 0.003		(10) 0.017	†	(10) 0.019	†
				SD	0.005		0.013		0.007	
	Recovery	22	-	Mean	(5) 0.008		(5) 0.008		(5) 0.008	
				SD	0.013		0.004		0.004	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2			3		
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day			30 µg /day		
LUC (10^3/uL)	Dosing	4	--	Mean	(7) 0.046		(7) 0.187	†		(7) 0.183	†	
				SD	0.011		0.139			0.104		
		17	-	Mean	(9) 0.026		(10) 0.209	†		(10) 0.323	†	
				SD	0.013		0.145			0.118		
	Recovery	22	-	Mean	(5) 0.034		(5) 0.048			(5) 0.026		
				SD	0.027		0.011			0.009		
PT_Rat (sec)	Dosing	17	-	Mean	(8) 14.64		(9) 15.63	*		(10) 16.35	†	
				SD	0.76		1.20			0.71		
	Recovery	22	-	Mean	(5) 15.34		(5) 16.64			(5) 18.68	*	
				SD	1.30		1.51			1.78		
APTT (sec)	Dosing	17	-	Mean	(8) 14.41		(9) 16.50	*		(10) 16.78	*	
				SD	1.81		2.65			1.78		
	Recovery	22	-	Mean	(5) 16.44		(5) 17.76	*		(5) 18.12	†	
				SD	0.50		0.79			0.67		
FIB (mg/dL)	Dosing	17	-	Mean	(8) 253.1		(9) 596.7	†		(10) 606.1	†	
				SD	14.3		39.6			53.9		

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
FIB (mg/dL)	Recovery	22	-	**Mean**	(5)	264.8	(5)	266.6	(5)	264.0
				SD		30.7		21.9		10.8

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2			3		
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day			30 µg /day		
RBC (10^6/uL)	Dosing	4	--	Mean	(7)	7.903	(7)	7.381	*	(7)	7.470	*
				SD		0.370		0.190			0.206	
		17	-	Mean	(10)	7.423	(9)	6.872	†	(7)	6.836	†
				SD		0.183		0.195			0.343	
	Recovery	22	-	Mean	(5)	7.262	(5)	7.838	†	(5)	7.704	*
				SD		0.267		0.256			0.208	
HGB (g/dL)	Dosing	4	--	Mean	(7)	14.53	(7)	13.56	*	(7)	13.56	*
				SD		0.59		0.62			0.58	
		17	-	Mean	(10)	13.83	(9)	12.38	†	(7)	12.24	†
				SD		0.31		0.34			0.68	
	Recovery	22	-	Mean	(5)	13.64	(5)	13.92		(5)	14.14	
				SD		0.67		0.37			0.57	
HCT (%)	Dosing	4	--	Mean	(7)	44.91	(7)	41.79	*	(7)	41.81	*
				SD		1.91		1.79			1.29	
		17	-	Mean	(10)	41.67	(9)	38.09	†	(7)	37.21	†
				SD		0.70		0.98			1.75	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day		30 µg /day	
HCT (%)	Recovery	22	-	Mean	(5) 40.78		(5) 42.46		(5) 42.98	
				SD	1.82		0.93		1.99	
MCV (fL)	Dosing	4	--	Mean	(7) 56.84		(7) 56.59		(7) 56.03	
				SD	0.87		1.75		1.91	
		17	-	Mean	(10) 56.16		(9) 55.43		(6) 54.40	
				SD	1.19		1.71		1.97	
	Recovery	22	-	Mean	(4) 55.80		(5) 54.22		(5) 55.78	
				SD	2.62		1.55		2.21	
MCH (pg)	Dosing	4	--	Mean	(7) 18.37		(7) 18.39		(7) 18.16	
				SD	0.22		0.67		0.75	
		17	-	Mean	(10) 18.62		(9) 17.99	†	(7) 17.89	†
				SD	0.35		0.49		0.60	
	Recovery	22	-	Mean	(5) 18.78		(5) 17.76		(5) 18.38	
				SD	0.97		0.38		0.82	
MCHC (g/dL)	Dosing	4	--	Mean	(7) 32.34		(7) 32.49		(7) 32.41	
				SD	0.30		0.78		0.63	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	**REF**		**2**		**3**	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
MCHC (g/dL)	Dosing	17	-	**Mean**	(10) 33.18		(9) 32.50	†	(7) 32.84	
				SD	0.32		0.41		0.59	
	Recovery	22	-	**Mean**	(5) 33.46		(5) 32.78		(5) 32.96	
				SD	0.56		0.33		0.75	
RDW (%)	Dosing	4	--	**Mean**	(7) 11.11		(7) 11.39		(7) 11.97	†
				SD	0.29		0.40		0.68	
		17	-	**Mean**	(10) 11.33		(9) 13.34	†	(6) 13.38	†
				SD	0.43		1.04		0.64	
	Recovery	22	-	**Mean**	(4) 10.80		(5) 13.04	†	(5) 13.32	†
				SD	0.33		0.23		0.50	
RETIC (10^3/uL)	Dosing	4	--	**Mean**	(7) 301.7		(7) 129.7	†	(7) 133.6	†
				SD	39.4		35.7		39.1	
		17	-	**Mean**	(10) 168.9		(9) 222.1	*	(7) 203.3	
				SD	34.7		54.7		45.8	
	Recovery	22	-	**Mean**	(5) 153.2		(5) 155.0		(5) 136.2	
				SD	36.2		16.0		49.9	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	**REF**		**2**		**3**	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
PLT (10^3/uL)	Dosing	4	--	**Mean**	(7) 927.1		(7) 1003.9		(7) 973.6	
				SD	116.6		70.9		168.1	
		17	-	**Mean**	(10) 906.9		(9) 778.0	*	(7) 757.6	
				SD	124.5		88.3		151.1	
	Recovery	22	-	**Mean**	(5) 787.6		(5) 838.2		(5) 782.0	
				SD	77.7		88.0		56.6	
MPV (fL)	Dosing	4	--	**Mean**	(7) 8.67		(7) 8.91		(7) 8.99	
				SD	0.91		0.25		0.81	
		17	-	**Mean**	(10) 9.50		(9) 9.40		(7) 9.73	
				SD	0.49		0.21		0.72	
	Recovery	22	-	**Mean**	(5) 9.20		(5) 9.02		(5) 9.18	
				SD	0.42		0.34		0.33	
WBC (10e3/uL)	Dosing	4	--	**Mean**	(7) 6.01		(7) 7.84		(7) 8.57	*
				SD	2.38		1.98		0.92	
		17	-	**Mean**	(10) 2.16		(9) 5.70	†	(7) 6.37	†
				SD	0.45		1.33		2.46	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	**REF**			**2**			**3**	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**			**30 µg/day**			**30 µg /day**	
WBC (10e3/uL)	Recovery	22	-	**Mean**	(5)	2.34	(5)	2.62		(5)	2.72	
				SD		0.87		0.69			1.16	
NEUT (10^3/uL)	Dosing	4	--	**Mean**	(7)	0.920	(7)	2.306		(7)	2.879	†
				SD		1.220		0.683			0.478	
		17	-	**Mean**	(10)	0.409	(9)	2.469	†	(7)	2.879	†
				SD		0.198		0.711			1.238	
	Recovery	22	-	**Mean**	(5)	0.252	(5)	0.482	*	(5)	0.278	
				SD		0.051		0.279			0.051	
LYM (10^3/uL)	Dosing	4	--	**Mean**	(7)	4.911	(7)	5.136		(7)	5.169	
				SD		1.263		1.368			0.932	
		17	-	**Mean**	(10)	1.651	(9)	2.833	†	(7)	3.030	†
				SD		0.289		0.872			1.209	
	Recovery	22	-	**Mean**	(5)	2.016	(5)	2.050		(5)	2.316	
				SD		0.899		0.554			1.068	
MONO (10^3/uL)	Dosing	4	--	**Mean**	(7)	0.093	(7)	0.176		(7)	0.234	†
				SD		0.092		0.054			0.062	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	**REF**		**2**		**3**	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
MONO (10^3/uL)	Dosing	17	-	**Mean**	(10) 0.056		(9) 0.154	†	(7) 0.176	†
				SD	0.025		0.033		0.068	
	Recovery	22	-	**Mean**	(5) 0.028		(5) 0.048		(5) 0.060	*
				SD	0.013		0.011		0.025	
EO (10^3/uL)	Dosing	4	--	**Mean**	(7) 0.057		(7) 0.087	*	(7) 0.123	†
				SD	0.011		0.023		0.039	
		17	-	**Mean**	(10) 0.029		(9) 0.092	†	(7) 0.097	†
				SD	0.013		0.043		0.042	
	Recovery	22	-	**Mean**	(5) 0.032		(5) 0.028		(5) 0.036	
				SD	0.011		0.011		0.021	
BASO (10^3/uL)	Dosing	4	--	**Mean**	(7) 0.009		(7) 0.017		(7) 0.024	†
				SD	0.007		0.010		0.005	
		17	-	**Mean**	(10) 0.001		(9) 0.008	†	(7) 0.010	†
				SD	0.003		0.004		0.006	
	Recovery	22	-	**Mean**	(5) 0.000		(5) 0.000		(5) 0.002	
				SD	0.000		0.000		0.004	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	**REF**		**2**		**3**	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
LUC (10^3/uL)	Dosing	4	--	**Mean**	(7) 0.030		(7) 0.126	†	(7) 0.133	†
				SD	0.028		0.093		0.060	
		17	-	**Mean**	(10) 0.010		(9) 0.132	†	(7) 0.190	†
				SD	0.005		0.101		0.096	
	Recovery	22	-	**Mean**	(5) 0.014		(5) 0.012		(5) 0.022	
				SD	0.005		0.008		0.016	
PT_Rat (sec)	Dosing	17	-	**Mean**	(10) 14.12		(9) 14.89		(9) 15.38	*
				SD	0.84		1.02		0.93	
	Recovery	22	-	**Mean**	(5) 13.10		(5) 13.66		(5) 13.58	
				SD	0.83		0.83		0.62	
APTT (sec)	Dosing	17	-	**Mean**	(10) 15.45		(9) 15.56		(9) 14.78	
				SD	0.80		1.39		3.08	
	Recovery	22	-	**Mean**	(5) 16.82		(5) 17.26		(5) 16.96	
				SD	0.85		0.90		0.72	
FIB (mg/dL)	Dosing	17	-	**Mean**	(10) 217.2		(9) 541.9	†	(9) 563.1	†
				SD	25.0		63.4		56.7	

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Table 6

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
FIB (mg/dL)	Recovery	22	-	**Mean**	(5)	186.4	(5)	196.6	(5)	185.0
				SD		17.2		18.4		16.6

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
ALP	Alkaline Phosphatase
GGT	Gamma Glutamyl Transferase
TBIL	Bilirubin, Total
CHOL	Cholesterol
TRIG	Triglycerides
GLUC	Glucose
TP	Protein, Total
ALB	Albumin
GLOB	Globulin
AG	Albumin/Globulin Ratio
BUN	Blood Urea Nitrogen
CREA	Creatinine
PHOS	Phosphorus
CA	Calcium
NA	Sodium
K	Potassium
CL	Chloride
A2M	Alpha-2-Macroglobulin

Parameter	Description
A1AGP	Alpha-1 Acid Glycoprotein

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Sample size is displayed in ( ) before the mean value.
SD = Standard Deviation; - = Value not applicable;
Units are displayed in the ( ) under each parameter name;
HPD = Hours Post Dose; U = Unscheduled;
e = Group mean excluded from statistics;
REF = Denotes group used as reference in the statistical test;
* = Statistically significant pairwise comparison at 0.05 level;
† = Statistically significant pairwise comparison at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level.
+ = Ascending trend sign;
- = Descending trend sign;
= Individual parameter values reported as less than or greater than limit of quantitation are set equal to the limit to calculate the average.

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2			3		
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day			30 µg /day		
ALT (U/L)	Dosing	4	---	Mean	(8)	29.1	(8)	33.3		(8)	28.8	
				SD		6.9		6.5			5.6	
		17	-	Mean	(10)	18.1	(10)	22.9	*	(10)	20.8	
				SD		2.4		4.7			3.0	
	Recovery	22	-	Mean	(5)	19.2	(5)	17.6		(5)	17.4	
				SD		3.3		2.5			3.0	
AST (U/L)	Dosing	4	---	Mean	(8)	94.5	(8)	103.1		(8)	97.8	
				SD		8.3		14.7			14.0	
		17	-	Mean	(10)	71.7	(10)	84.2	*	(10)	86.8	†
				SD		5.3		15.4			8.5	
	Recovery	22	-	Mean	(5)	91.8	(5)	94.0		(5)	97.0	
				SD		10.3		13.5			4.6	
ALP (U/L)	Dosing	4	---	Mean	(8)	166.6	(8)	195.4	*	(8)	188.3	
				SD		50.3		28.2			29.0	
		17	-	Mean	(10)	97.6	(10)	103.4		(10)	110.0	
				SD		25.9		18.9			22.8	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
ALP (U/L)	Recovery	22	-	**Mean**	(5)	84.4	(5)	79.6	(5)	83.4
				SD		17.0		9.3		18.6
GGT (U/L)	Dosing	4	---	**Mean**	(8)	3.0	(8)	3.0	(8)	3.0
				SD	#	0.0	#	0.0	#	0.0
		17	-	**Mean**	(10)	3.0	(10)	3.0	(10)	3.0
				SD	#	0.0	#	0.0	#	0.0
	Recovery	22	-	**Mean**	(5)	3.0	(5)	3.0	(5)	3.0
				SD	#	0.0	#	0.0	#	0.0
TBIL (mg/dL)	Dosing	4	---	**Mean**	(8)	0.10	(8)	0.10	(8)	0.10
				SD	#	0.00	#	0.00	#	0.00
		17	-	**Mean**	(10)	0.10	(10)	0.10	(10)	0.10
				SD	#	0.00	#	0.00	#	0.00
	Recovery	22	-	**Mean**	(5)	0.10	(5)	0.10	(5)	0.10
				SD	#	0.00	#	0.00	#	0.00
CHOL (mg/dL)	Dosing	4	---	**Mean**	(8)	63.0	(8)	52.5	(8)	51.8
				SD		9.3		7.2		15.3

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	**REF**		**2**			**3**		
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**			**30 µg /day**		
CHOL (mg/dL)	Dosing	17	-	**Mean**	(10)	51.7	(10)	40.2	†	(10)	37.2	†
				SD		6.7		6.1			8.6	
	Recovery	22	-	**Mean**	(5)	52.8	(5)	61.0	*	(5)	56.2	
				SD		7.2		5.7			4.4	
TRIG (mg/dL)	Dosing	4	---	**Mean**	(8)	62.0	(8)	42.8		(8)	51.9	
				SD		25.8		10.2			19.6	
		17	-	**Mean**	(10)	58.8	(10)	33.6	†	(10)	35.9	†
				SD		16.6		7.2			10.3	
	Recovery	22	-	**Mean**	(5)	49.0	(5)	50.8		(5)	45.6	
				SD		18.4		15.1			16.0	
GLUC (mg/dL)	Dosing	4	---	**Mean**	(8)	111.3	(8)	98.1		(8)	100.0	
				SD		14.2		12.6			16.7	
		17	-	**Mean**	(10)	131.7	(10)	117.4		(10)	122.6	
				SD		17.0		17.0			23.9	
	Recovery	22	-	**Mean**	(5)	137.0	(5)	121.4		(5)	119.8	
				SD		30.1		23.7			16.1	

Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2			3		
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day			30 µg /day		
TP (g/dL)	Dosing	4	---	Mean	(8)	6.10	(8)	5.90		(8)	5.85	
				SD		0.21		0.22			0.22	
		17	-	Mean	(10)	5.39	(10)	5.51		(10)	5.41	
				SD		0.30		0.36			0.34	
	Recovery	22	-	Mean	(5)	5.82	(5)	6.08	*	(5)	5.90	
				SD		0.16		0.11			0.14	
ALB (g/dL)	Dosing	4	---	Mean	(8)	3.98	(8)	3.71	†	(8)	3.68	†
				SD		0.14		0.15			0.14	
		17	-	Mean	(10)	3.50	(10)	3.43		(10)	3.38	
				SD		0.19		0.21			0.22	
	Recovery	22	-	Mean	(5)	3.72	(5)	3.82		(5)	3.72	
				SD		0.11		0.08			0.13	
GLOB (g/dL)	Dosing	4	---	Mean	(8)	2.13	(8)	2.19		(8)	2.18	
				SD		0.09		0.10			0.10	
		17	-	Mean	(10)	1.89	(10)	2.08	*	(10)	2.03	
				SD		0.12		0.18			0.13	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2			3		
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day			30 µg /day		
GLOB (g/dL)	Recovery	22	-	Mean	(5)	2.10	(5)	2.26	†	(5)	2.18	
				SD		0.07		0.05			0.04	
AG (None)	Dosing	4	---	Mean	(8)	1.88	(8)	1.70	†	(8)	1.69	†
				SD		0.07		0.08			0.06	
		17	-	Mean	(10)	1.85	(10)	1.65	†	(10)	1.65	†
				SD		0.05		0.08			0.05	
	Recovery	22	-	Mean	(5)	1.76	(5)	1.72		(5)	1.70	
				SD		0.05		0.04			0.07	
BUN (mg/dL)	Dosing	4	---	Mean	(8)	23.8	(8)	26.0		(8)	23.8	
				SD		5.0		4.0			2.7	
		17	-	Mean	(10)	18.8	(10)	18.6		(10)	19.9	
				SD		3.9		3.2			2.8	
	Recovery	22	-	Mean	(5)	17.0	(5)	17.2		(5)	16.4	
				SD		1.7		1.3			3.8	
CREA (mg/dL)	Dosing	4	---	Mean	(8)	0.31	(8)	0.29		(8)	0.26	*
				SD		0.04		0.04			0.05	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
CREA (mg/dL)	Dosing	17	-	**Mean**	(10)	0.25	(10)	0.25	(10)	0.27
				SD		0.05		0.07		0.05
	Recovery	22	-	**Mean**	(5)	0.28	(5)	0.28	(5)	0.28
				SD		0.04		0.04		0.04
PHOS (mg/dL)	Dosing	4	---	**Mean**	(8)	7.34	(8)	7.41	(8)	7.58
				SD		0.56		0.45		0.38
		17	-	**Mean**	(10)	8.72	(10)	8.11	(10)	8.01
				SD		0.75		0.58		0.92
	Recovery	22	-	**Mean**	(5)	6.56	(5)	6.86	(5)	6.82
				SD		1.15		0.46		0.72
CA (mg/dL)	Dosing	4	---	**Mean**	(8)	9.76	(8)	9.65	(8)	9.75
				SD		0.25		0.28		0.32
		17	-	**Mean**	(10)	9.86	(10)	9.82	(10)	9.59
				SD		0.34		0.35		0.30
	Recovery	22	-	**Mean**	(5)	9.44	(5)	9.44	(5)	9.48
				SD		0.11		0.29		0.27

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
NA (mmol/L)	Dosing	4	---	**Mean**	(8)	144.4	(8)	144.1	(8)	143.8
				SD		1.6		1.4		1.2
		17	-	**Mean**	(10)	144.0	(10)	142.3	(10)	142.7
				SD		1.2		1.9		1.9
	Recovery	22	-	**Mean**	(5)	142.4	(5)	142.6	(5)	143.4
				SD		0.5		0.9		0.9
K (mmol/L)	Dosing	4	---	**Mean**	(8)	4.45	(8)	4.55	(8)	4.66
				SD		0.31		0.18		0.29
		17	-	**Mean**	(10)	4.30	(10)	4.36	(10)	4.32
				SD		0.16		0.31		0.19
	Recovery	22	-	**Mean**	(5)	4.12	(5)	4.26	(5)	4.20
				SD		0.28		0.26		0.20
CL (mmol/L)	Dosing	4	---	**Mean**	(8)	102.4	(8)	102.0	(8)	101.3
				SD		2.8		0.9		1.3
		17	-	**Mean**	(10)	104.8	(10)	103.4	(10)	104.2
				SD		0.9		1.8		1.3

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
CL (mmol/L)	Recovery	22	-	**Mean**	(5) 105.6		(5) 106.0		(5) 106.4	
				SD	1.5		1.0		1.1	
A2M (ug/mL)	Dosing	4	---	**Mean**	(8) 113.4		(8) 2318.1	†	(8) 3911.6	†
				SD	228.9		922.4		2866.1	
		17	-	**Mean**	(10) 14.0		(10) 990.6	†	(10) 1794.2	†
				SD	3.3		730.0		1234.1	
	Recovery	22	-	**Mean**	(5) 8.0		(5) 19.4	*	(5) 16.2	†
				SD	1.9		14.3		2.3	
A1AGP (ug/mL)	Dosing	4	---	**Mean**	(8) 174.358		(8) 1642.265	†	(8) 2351.791	†
				SD	312.769		312.914		1053.465	
		17	-	**Mean**	(10) 47.672		(10) 1835.986	†	(10) 2021.083	†
				SD	12.664		372.467		673.967	
	Recovery	22	-	**Mean**	(5) 54.910		(5) 75.740		(5) 62.562	
				SD	20.556		26.083		16.549	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
ALT (U/L)	Dosing	4	---	**Mean**	(8) 20.9		(8) 24.9		(8) 23.1	
				SD	4.3		4.3		5.2	
		17	-	**Mean**	(9) 11.3		(9) 13.9	†	(8) 16.5	†
				SD	1.3		2.1		3.3	
	Recovery	22	-	**Mean**	(5) 11.8		(5) 14.8		(5) 13.6	
				SD	2.2		2.2		1.8	
AST (U/L)	Dosing	4	---	**Mean**	(8) 81.8		(8) 96.1		(8) 91.3	
				SD	11.5		14.6		10.4	
		17	-	**Mean**	(9) 69.9		(9) 81.7		(8) 80.3	
				SD	18.3		15.9		18.0	
	Recovery	22	-	**Mean**	(5) 65.4		(5) 73.6		(5) 67.2	
				SD	8.2		10.2		4.4	
ALP (U/L)	Dosing	4	---	**Mean**	(8) 92.9		(8) 137.9	†	(8) 143.4	†
				SD	21.7		21.4		31.1	
		17	-	**Mean**	(9) 50.9		(9) 78.1	†	(8) 97.4	†
				SD	10.3		17.7		18.8	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
ALP (U/L)	Recovery	22	-	**Mean**	(5)	34.0	(5)	37.0	(5)	29.0
				SD		6.2		6.4		7.6
GGT (U/L)	Dosing	4	---	**Mean**	(8)	3.0	(8)	3.0	(8)	3.0
				SD	#	0.0	#	0.0	#	0.0
		17	-	**Mean**	(9)	3.0	(9)	3.0	(8)	3.0
				SD	#	0.0	#	0.0	#	0.0
	Recovery	22	-	**Mean**	(5)	3.0	(5)	3.0	(5)	3.0
				SD	#	0.0	#	0.0	#	0.0
TBIL (mg/dL)	Dosing	4	---	**Mean**	(8)	0.10	(8)	0.10	(8)	0.10
				SD	#	0.00	#	0.00	#	0.00
		17	-	**Mean**	(9)	0.10	(9)	0.10	(8)	0.10
				SD	#	0.00	#	0.00	#	0.00
	Recovery	22	-	**Mean**	(5)	0.10	(5)	0.10	(5)	0.10
				SD	#	0.00	#	0.00	#	0.00
CHOL (mg/dL)	Dosing	4	---	**Mean**	(8)	45.6	(8)	47.3	(8)	56.6
				SD		13.4		12.3		12.4

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

	Phase	Day	HPD	Group Number: / Dose :	REF 0 µg/day		2 30 µg/day		3 30 µg /day	
CHOL (mg/dL)	Dosing	17	-	Mean	(9) 33.4		(9) 33.7		(8) 31.9	
				SD	11.5		6.3		4.2	
	Recovery	22	-	Mean	(5) 43.0		(5) 54.2		(5) 41.2	
				SD	13.0		18.9		8.6	
TRIG (mg/dL)	Dosing	4	---	Mean	(8) 36.8		(8) 29.4		(8) 34.5	
				SD	13.0		6.8		7.8	
		17	-	Mean	(9) 27.8		(9) 25.1		(8) 26.5	
				SD	8.4		5.1		5.1	
	Recovery	22	-	Mean	(5) 30.8		(5) 31.8		(5) 37.2	
				SD	8.7		3.7		7.9	
GLUC (mg/dL)	Dosing	4	---	Mean	(8) 102.5		(8) 89.1	†	(8) 87.1	†
				SD	8.4		8.2		5.9	
		17	-	Mean	(9) 111.4		(9) 99.7		(8) 99.5	
				SD	16.4		7.7		8.8	
	Recovery	22	-	Mean	(5) 119.4		(5) 107.6		(5) 118.0	
				SD	14.3		10.7		22.2	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
TP (g/dL)	Dosing	4	---	**Mean**	(8) 6.26		(8) 5.65	†	(8) 5.94	
				SD	0.35		0.17		0.23	
		17	-	**Mean**	(9) 5.44		(9) 4.98	†	(8) 4.96	†
				SD	0.32		0.21		0.29	
	Recovery	22	-	**Mean**	(5) 6.52		(5) 6.54		(5) 6.74	
				SD	0.37		0.21		0.30	
ALB (g/dL)	Dosing	4	---	**Mean**	(8) 4.16		(8) 3.56	†	(8) 3.73	†
				SD	0.23		0.09		0.14	
		17	-	**Mean**	(9) 3.60		(9) 3.07	†	(8) 3.09	†
				SD	0.19		0.11		0.14	
	Recovery	22	-	**Mean**	(5) 4.26		(5) 4.14		(5) 4.32	
				SD	0.32		0.11		0.19	
GLOB (g/dL)	Dosing	4	---	**Mean**	(8) 2.10		(8) 2.09		(8) 2.21	
				SD	0.14		0.08		0.10	
		17	-	**Mean**	(9) 1.84		(9) 1.91		(8) 1.88	
				SD	0.15		0.12		0.18	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	Day	HPD	Dose :	0 µg/day		30 µg/day		30 µg /day	
GLOB (g/dL)	Recovery	22	-	Mean	(5) 2.26		(5) 2.40		(5) 2.42	
				SD	0.11		0.10		0.13	
AG (None)	Dosing	4	---	Mean	(8) 1.98		(8) 1.71	†	(8) 1.69	†
				SD	0.07		0.04		0.04	
		17	-	Mean	(9) 1.96		(9) 1.61	†	(8) 1.66	†
				SD	0.12		0.06		0.12	
	Recovery	22	-	Mean	(5) 1.90		(5) 1.72	*	(5) 1.80	
				SD	0.16		0.04		0.07	
BUN (mg/dL)	Dosing	4	---	Mean	(8) 16.8		(8) 18.8		(8) 18.3	
				SD	1.9		4.2		2.5	
		17	-	Mean	(9) 17.0		(9) 18.9		(8) 20.0	
				SD	3.0		3.3		1.3	
	Recovery	22	-	Mean	(5) 16.6		(5) 18.4		(5) 18.2	
				SD	3.0		2.7		1.8	
CREA (mg/dL)	Dosing	4	---	Mean	(8) 0.31		(8) 0.23	†	(8) 0.25	*
				SD	0.04		0.05		0.05	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
CREA (mg/dL)	Dosing	17	-	**Mean**	(9)	0.27	(9)	0.22	(8)	0.21
				SD		0.07		0.04		0.04
	Recovery	22	-	**Mean**	(5)	0.36	(5)	0.30	(5)	0.32
				SD		0.05		0.00		0.04
PHOS (mg/dL)	Dosing	4	---	**Mean**	(8)	6.61	(8)	6.81	(8)	6.91
				SD		0.56		0.57		0.57
		17	-	**Mean**	(9)	7.37	(9)	7.38	(8)	7.73
				SD		0.95		0.55		1.03
	Recovery	22	-	**Mean**	(5)	6.48	(5)	6.30	(5)	6.76
				SD		0.78		0.88		0.94
CA (mg/dL)	Dosing	4	---	**Mean**	(8)	9.70	(8)	9.59	(8)	9.81
				SD		0.26		0.18		0.29
		17	-	**Mean**	(9)	9.52	(9)	9.53	(8)	9.65
				SD		0.14		0.27		0.27
	Recovery	22	-	**Mean**	(5)	9.76	(5)	9.80	(5)	9.82
				SD		0.30		0.12		0.31

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
NA (mmol/L)	Dosing	4	---	**Mean**	(8) 143.8		(8) 143.1		(8) 143.8	
				SD	0.9		1.0		1.4	
		17	-	**Mean**	(9) 143.6		(9) 143.0		(8) 143.1	
				SD	1.1		1.3		0.8	
	Recovery	22	-	**Mean**	(5) 142.2		(5) 143.2		(5) 142.8	
				SD	1.9		0.8		1.3	
K (mmol/L)	Dosing	4	---	**Mean**	(8) 3.85		(8) 4.33	†	(8) 4.39	†
				SD	0.14		0.37		0.36	
		17	-	**Mean**	(9) 4.46		(9) 4.53		(8) 4.75	
				SD	0.28		0.18		0.24	
	Recovery	22	-	**Mean**	(5) 3.84		(5) 4.00		(5) 4.00	
				SD	0.32		0.16		0.22	
CL (mmol/L)	Dosing	4	---	**Mean**	(8) 104.1		(8) 104.5		(8) 105.1	
				SD	1.4		1.8		2.0	
		17	-	**Mean**	(9) 108.0		(9) 107.7		(8) 108.1	
				SD	1.0		1.8		1.2	

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Table 7

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

				Group Number:	REF		2		3	
	Phase	**Day**	**HPD**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
CL (mmol/L)	Recovery	22	-	**Mean**	(5) 106.8		(5) 106.0		(5) 106.8	
				SD	2.3		1.2		0.8	
A2M (ug/mL)	Dosing	4	---	**Mean**	(8) 212.1		(8) 703.8	†	(8) 887.1	†
				SD	241.1		396.4		352.9	
		17	-	**Mean**	(10) 33.1		(9) 521.0	†	(8) 592.0	†
				SD	49.7		260.6		243.7	
	Recovery	22	-	**Mean**	(5) 17.2		(5) 16.2		(5) 16.0	
				SD	8.5		5.7		4.3	
A1AGP (ug/mL)	Dosing	4	---	**Mean**	(8) 239.774		(8) 1906.314	†	(8) 1677.103	†
				SD	176.264		376.234		269.796	
		17	-	**Mean**	(10) 95.959		(9) 1491.849	†	(8) 1651.071	†
				SD	82.718		326.518		404.600	
	Recovery	22	-	**Mean**	(5) 62.788		(5) 47.912		(5) 57.588	
				SD	18.725		12.620		19.626	

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Table 8

Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description
pH	pH
SG	Specific Gravity
VOLUME	Total Volume

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Table 8

Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Sample size is displayed in ( ) before the mean value.
SD = Standard Deviation; - = Value not applicable;
Units are displayed in the ( ) under each parameter name;
HPD = Hours Post Dose; U = Unscheduled;
e = Group mean excluded from statistics;
REF = Denotes group used as reference in the statistical test;
* = Statistically significant pairwise comparison at 0.05 level;
† = Statistically significant pairwise comparison at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level.
+ = Ascending trend sign;
- = Descending trend sign;
= Individual parameter values reported as less than or greater than limit of quantitation are set equal to the limit to calculate the average.

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Table 8

Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

			Group Number:	REF		2		3	
	Phase	**Day**	**Dose :**	**0 µg/day**		**30 µg/day**		**30 µg /day**	
pH (None)	Dosing	17	**Mean**	(10) 7.10		(10) 6.75		(10) 6.60	†
			SD	0.39		0.35		0.32	
	Recovery	22	**Mean**	(5) 7.30		(5) 7.20		(5) 7.00	
			SD	0.45		0.27		0.35	
SG (None)	Dosing	17	**Mean**	(10) 1.0322		(10) 1.0260		(10) 1.0282	
			SD	0.0205		0.0227		0.0183	
	Recovery	22	**Mean**	(5) 1.0556		(5) 1.0340	*	(5) 1.0440	
			SD	0.0038		0.0146		0.0234	
VOLUME (mL)	Dosing	17	**Mean**	(10) 14.90		(10) 17.80		(10) 11.60	
			SD	15.54		16.95		6.88	
	Recovery	22	**Mean**	(5) 3.70		(5) 8.20		(5) 8.00	
			SD	0.97		5.50		10.68	

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Table 8

Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

	Phase	Day	Group Number:	REF		2		3	
			Dose :	0 µg/day		30 µg/day		30 µg /day	
pH (None)	Dosing	17	**Mean**	(10) 6.75		(10) 6.20	†	(10) 6.20	†
			SD	0.26		0.26		0.35	
	Recovery	22	**Mean**	(5) 7.00		(5) 6.60		(5) 6.50	
			SD	0.61		0.65		0.35	
SG (None)	Dosing	17	**Mean**	(10) 1.0243		(10) 1.0288		(10) 1.0250	
			SD	0.0128		0.0164		0.0140	
	Recovery	22	**Mean**	(5) 1.0240		(5) 1.0364		(5) 1.0276	
			SD	0.0174		0.0177		0.0198	
VOLUME (mL)	Dosing	17	**Mean**	(10) 9.90		(10) 9.60		(10) 9.40	
			SD	7.03		9.05		6.98	
	Recovery	22	**Mean**	(5) 11.00		(5) 6.00		(5) 9.00	
			SD	7.38		5.09		7.52	

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

ABS = Absolute Value; OW = Organ Weight; BWT = Body Weight; BRN = Brain Weight; OW:BW = (g/g)*100; OW:BRN = g/g.
- = Value not applicable; N = Sample Size; Ratio = Group Mean / Reference Group Mean; R REF = Denotes group used as reference in the ratio calculations; SD = Standard Deviation;
REF = Denotes group used as reference in the statistical test;
e = Group mean excluded from statistics;
@ = Number examined reduced due to excluded data;
* = Statistically significant pairwise comparision at 0.05 level;
† = Statistically significant pairwise comparision at 0.01 level;
‡ = Statistically significant trend at 0.05 level;
§ = Statistically significant trend at 0.01 level;
+ = Ascending trend sign;
- = Descending trend sign;

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male - Dosing - Terminal Euthanasia

Group Number: / Dose:		REF 0 µg/day				2 30 µg/day					3 30 µg /day				
		N	Mean	Ratio	SD	N	Mean	Ratio	SD		N	Mean	Ratio	SD	
BWT	ABS	10	296.06	R REF	16.40	10	271.17	0.92	17.12	†	10	262.59	0.89	18.67	†
Brain	ABS	10	1.9061	R REF	0.0899	10	1.9159	1.01	0.1445		10	1.9082	1.00	0.0599	
	OW:BW	10	0.6449	R REF	0.0335	10	0.7087	1.10	0.0664	†	10	0.7294	1.13	0.0481	†
	OW:BRN	10	1.0000	R REF	0.0000	10	1.0000	1.00	0.0000		10	1.0000	1.00	0.0000	
Epididymis	ABS	10	1.1647	R REF	0.1713	10	1.0626	0.91	0.1281		10	1.0508	0.90	0.0665	
	OW:BW	10	0.3936	R REF	0.0536	10	0.3922	1.00	0.0428		10	0.4026	1.02	0.0442	
	OW:BRN	10	0.6112	R REF	0.0867	10	0.5570	0.91	0.0756		10	0.5512	0.90	0.0400	
Gland, Adrenal	ABS	10	0.0697	R REF	0.0068	10	0.0727	1.04	0.0149		10	0.0706	1.01	0.0107	
	OW:BW	10	0.0236	R REF	0.0021	10	0.0267	1.13	0.0045		10	0.0270	1.14	0.0044	
	OW:BRN	10	0.0366	R REF	0.0040	10	0.0383	1.04	0.0091		10	0.0371	1.01	0.0061	
Gland, Prostate	ABS	10	0.7215	R REF	0.1036	10	0.7324	1.02	0.2129		10	0.6755	0.94	0.1088	
	OW:BW	10	0.2439	R REF	0.0328	10	0.2699	1.11	0.0726		10	0.2575	1.06	0.0401	
	OW:BRN	10	0.3781	R REF	0.0476	10	0.3808	1.01	0.0941		10	0.3539	0.94	0.0556	
Heart	ABS	10	0.9152	R REF	0.0698	10	0.9242	1.01	0.1151		10	0.8795	0.96	0.1051	
	OW:BW	10	0.3097	R REF	0.0260	10	0.3405	1.10	0.0329	*	10	0.3346	1.08	0.0278	
	OW:BRN	10	0.4807	R REF	0.0388	10	0.4852	1.01	0.0758		10	0.4614	0.96	0.0583	
Kidney	ABS	10	2.1659	R REF	0.1836	10	2.2197	1.02	0.2229		10	2.0252	0.94	0.1974	
	OW:BW	10	0.7312	R REF	0.0411	10	0.8179	1.12	0.0507	†	10	0.7710	1.05	0.0495	
	OW:BRN	10	1.1356	R REF	0.0682	10	1.1600	1.02	0.0939		10	1.0607	0.93	0.0914	
Liver	ABS	10	8.3218	R REF	0.5205	10	7.7880	0.94	0.4860	*	10	7.5872	0.91	0.5920	†
	OW:BW	10	2.8131	R REF	0.1435	10	2.8771	1.02	0.1801		10	2.8905	1.03	0.1234	
	OW:BRN	10	4.3681	R REF	0.2325	10	4.0850	0.94	0.3960		10	3.9783	0.91	0.3168	*
Spleen	ABS	10	0.5951	R REF	0.0613	10	0.7700	1.29	0.1038	†	10	0.7984	1.34	0.0899	†
	OW:BW	10	0.2008	R REF	0.0147	10	0.2842	1.42	0.0352	†	10	0.3051	1.52	0.0373	†
	OW:BRN	10	0.3120	R REF	0.0264	10	0.4019	1.29	0.0431	†	10	0.4191	1.34	0.0521	†

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male - Dosing - Terminal Euthanasia

	Group Number:	REF				2				3				
	Dose:	0 µg/day				30 µg/day				30 µg /day				
		N	Mean	Ratio	SD	N	Mean	Ratio	SD		N	Mean	Ratio	SD	
Testis	ABS	10	3.2727	R REF	0.3106	10	3.4683	1.06	0.3109		10	3.2716	1.00	0.2275	
	OW:BW	10	1.1090	R REF	0.1254	10	1.2803	1.15	0.1001	*	10	1.2538	1.13	0.1447	*
	OW:BRN	10	1.7171	R REF	0.1440	10	1.8123	1.06	0.1262		10	1.7146	1.00	0.1080	
Thymus	ABS	10	0.5914	R REF	0.0676	10	0.4673	0.79	0.0934	†	10	0.4200	0.71	0.0907	†
	OW:BW	10	0.1999	R REF	0.0222	10	0.1718	0.86	0.0293	*	10	0.1591	0.80	0.0275	†
	OW:BRN	10	0.3098	R REF	0.0266	10	0.2448	0.79	0.0507	†	10	0.2199	0.71	0.0460	†

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male - Recovery - Recovery Euthanasia 1

Group Number: / Dose:		REF 0 µg/day				2 30 µg/day					3 30 µg /day				
		N	Mean	Ratio	SD	N	Mean	Ratio	SD		N	Mean	Ratio	SD	
BWT	ABS	5	331.78	R REF	39.66	5	351.50	1.06	17.44		5	334.36	1.01	13.43	
Brain	ABS	5	2.1072	R REF	0.0471	5	1.9590	0.93	0.1319	*	5	1.9408	0.92	0.0143	†
	OW:BW	5	0.6419	R REF	0.0712	5	0.5582	0.87	0.0441		5	0.5813	0.91	0.0261	
	OW:BRN	5	1.0000	R REF	0.0000	5	1.0000	1.00	0.0000		5	1.0000	1.00	0.0000	
Epididymis	ABS	5	1.3602	R REF	0.1271	5	1.2546	0.92	0.1995		5	1.4004	1.03	0.0631	
	OW:BW	5	0.4136	R REF	0.0519	5	0.3560	0.86	0.0450	*	5	0.4189	1.01	0.0134	
	OW:BRN	5	0.6457	R REF	0.0612	5	0.6387	0.99	0.0765		5	0.7216	1.12	0.0323	
Gland, Adrenal	ABS	5	0.0670	R REF	0.0112	5	0.0904	1.35	0.0185		5	0.0768	1.15	0.0144	
	OW:BW	5	0.0202	R REF	0.0026	5	0.0258	1.28	0.0058		5	0.0231	1.14	0.0050	
	OW:BRN	5	0.0318	R REF	0.0050	5	0.0458	1.44	0.0067	†	5	0.0396	1.25	0.0074	
Gland, Prostate	ABS	5	1.1332	R REF	0.2539	5	1.0192	0.90	0.1756		5	1.0446	0.92	0.1737	
	OW:BW	5	0.3431	R REF	0.0795	5	0.2913	0.85	0.0589		5	0.3129	0.91	0.0557	
	OW:BRN	5	0.5380	R REF	0.1211	5	0.5201	0.97	0.0778		5	0.5384	1.00	0.0901	
Heart	ABS	5	1.0268	R REF	0.2019	5	1.0990	1.07	0.0611		5	1.0652	1.04	0.0604	
	OW:BW	5	0.3078	R REF	0.0309	5	0.3133	1.02	0.0245		5	0.3189	1.04	0.0201	
	OW:BRN	5	0.4869	R REF	0.0925	5	0.5615	1.15	0.0143		5	0.5490	1.13	0.0342	
Kidney	ABS	5	2.4058	R REF	0.3649	5	2.3406	0.97	0.0687		5	2.2832	0.95	0.1908	
	OW:BW	5	0.7230	R REF	0.0289	5	0.6673	0.92	0.0403		5	0.6832	0.94	0.0571	
	OW:BRN	5	1.1410	R REF	0.1662	5	1.1975	1.05	0.0516		5	1.1770	1.03	0.1060	
Liver	ABS	5	8.5896	R REF	1.3878	5	8.9672	1.04	0.5403		5	8.7588	1.02	0.5137	
	OW:BW	5	2.5818	R REF	0.1539	5	2.5516	0.99	0.1092		5	2.6186	1.01	0.0777	
	OW:BRN	5	4.0739	R REF	0.6314	5	4.5995	1.13	0.4799		5	4.5142	1.11	0.2862	
Spleen	ABS	5	0.6086	R REF	0.0454	5	0.7230	1.19	0.0476	*	5	0.6604	1.09	0.1194	
	OW:BW	5	0.1856	R REF	0.0272	5	0.2057	1.11	0.0079		5	0.1980	1.07	0.0382	
	OW:BRN	5	0.2891	R REF	0.0253	5	0.3698	1.28	0.0248	*	5	0.3401	1.18	0.0606	

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male - Recovery - Recovery Euthanasia 1

	Group Number:	REF				2				3				
	Dose:	0 µg/day				30 µg/day				30 µg /day				
		N	Mean	Ratio	SD	N	Mean	Ratio	SD	N	Mean	Ratio	SD	
Testis	ABS	5	3.5472	R REF	0.2609	5	3.4582	0.97	0.3788	5	3.6938	1.04	0.2452	
	OW:BW	5	1.0751	R REF	0.0770	5	0.9839	0.92	0.0993	5	1.1070	1.03	0.0983	
	OW:BRN	5	1.6837	R REF	0.1236	5	1.7619	1.05	0.0966	5	1.9027	1.13	0.1141	*
Thymus	ABS	5	0.4938	R REF	0.0870	5	0.5536	1.12	0.0604	5	0.4270	0.86	0.0750	
	OW:BW	5	0.1515	R REF	0.0380	5	0.1572	1.04	0.0103	5	0.1284	0.85	0.0268	
	OW:BRN	5	0.2348	R REF	0.0438	5	0.2833	1.21	0.0326	5	0.2198	0.94	0.0371	

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female - Dosing - Terminal Euthanasia

Group Number:		REF				2				3				
Dose:		0 µg/day				30 µg/day				30 µg /day				
		N	Mean	Ratio	SD	N	Mean	Ratio	SD	N	Mean	Ratio	SD	
BWT	ABS	10	198.73	R REF	10.80	10	194.56	0.98	10.69	10	191.82	0.97	7.14	
Brain	ABS	10	1.8610	R REF	0.0694	10	1.7868	0.96	0.0595	10	1.8407	0.99	0.0783	
	OW:BW	10	0.9383	R REF	0.0507	10	0.9203	0.98	0.0467	10	0.9604	1.02	0.0451	
	OW:BRN	10	1.0000	R REF	0.0000	10	1.0000	1.00	0.0000	10	1.0000	1.00	0.0000	
Gland, Adrenal	ABS	10	0.0882	R REF	0.0162	10	0.0886	1.00	0.0156	9@	0.0907	1.03	0.0192	
	OW:BW	10	0.0442	R REF	0.0068	10	0.0454	1.03	0.0065	9@	0.0471	1.07	0.0090	
	OW:BRN	10	0.0474	R REF	0.0088	10	0.0496	1.05	0.0085	9@	0.0490	1.03	0.0100	
Heart	ABS	10	0.7450	R REF	0.0803	10	0.7573	1.02	0.0866	10	0.7173	0.96	0.0860	
	OW:BW	10	0.3749	R REF	0.0343	10	0.3893	1.04	0.0417	10	0.3736	1.00	0.0387	
	OW:BRN	10	0.4004	R REF	0.0418	10	0.4248	1.06	0.0563	10	0.3903	0.97	0.0491	
Kidney	ABS	10	1.5273	R REF	0.0808	10	1.6343	1.07	0.0778	* 10	1.6164	1.06	0.1416	
	OW:BW	10	0.7696	R REF	0.0415	10	0.8412	1.09	0.0418	† 10	0.8417	1.09	0.0529	†
	OW:BRN	10	0.8216	R REF	0.0519	10	0.9153	1.11	0.0477	† 10	0.8787	1.07	0.0758	
Liver	ABS	10	5.4571	R REF	0.3313	10	5.6490	1.04	0.5559	10	5.8104	1.06	0.4922	
	OW:BW	10	2.7466	R REF	0.0920	10	2.9002	1.06	0.1853	* 10	3.0247	1.10	0.1541	†
	OW:BRN	10	2.9329	R REF	0.1468	10	3.1630	1.08	0.3132	10	3.1580	1.08	0.2526	
Ovary	ABS	10	0.1167	R REF	0.0158	10	0.1053	0.90	0.0180	9@	0.1113	0.95	0.0170	
	OW:BW	10	0.0588	R REF	0.0076	10	0.0542	0.92	0.0097	9@	0.0579	0.98	0.0073	
	OW:BRN	10	0.0627	R REF	0.0079	10	0.0590	0.94	0.0101	9@	0.0601	0.96	0.0085	
Spleen	ABS	10	0.4382	R REF	0.0669	10	0.6796	1.55	0.1031	† 10	0.6199	1.41	0.0555	†
	OW:BW	10	0.2202	R REF	0.0294	10	0.3492	1.59	0.0489	† 10	0.3231	1.47	0.0261	†
	OW:BRN	10	0.2353	R REF	0.0333	10	0.3803	1.62	0.0550	† 10	0.3374	1.43	0.0337	†
Thymus	ABS	10	0.4588	R REF	0.0700	10	0.3967	0.86	0.1131	10	0.3906	0.85	0.0582	
	OW:BW	10	0.2310	R REF	0.0336	10	0.2031	0.88	0.0583	10	0.2036	0.88	0.0288	
	OW:BRN	10	0.2469	R REF	0.0386	10	0.2221	0.90	0.0655	10	0.2127	0.86	0.0324	

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Table 9

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female - Recovery - Recovery Euthanasia 1

Group Number: / Dose:		REF 0 µg/day				2 30 µg/day				3 30 µg /day				
		N	Mean	Ratio	SD	N	Mean	Ratio	SD	N	Mean	Ratio	SD	
BWT	ABS	5	213.64	R REF	15.61	5	213.36	1.00	6.07	5	210.36	0.98	19.63	
Brain	ABS	5	1.8336	R REF	0.1056	5	1.8732	1.02	0.1365	5	1.8450	1.01	0.0498	
	OW:BW	5	0.8609	R REF	0.0667	5	0.8788	1.02	0.0719	5	0.8846	1.03	0.1043	
	OW:BRN	5	1.0000	R REF	0.0000	5	1.0000	1.00	0.0000	5	1.0000	1.00	0.0000	
Gland, Adrenal	ABS	5	0.0866	R REF	0.0097	5	0.0904	1.04	0.0139	5	0.0900	1.04	0.0072	
	OW:BW	5	0.0407	R REF	0.0058	5	0.0424	1.04	0.0066	5	0.0431	1.06	0.0051	
	OW:BRN	5	0.0473	R REF	0.0048	5	0.0484	1.03	0.0084	5	0.0489	1.03	0.0049	
Heart	ABS	5	0.7312	R REF	0.0549	5	0.8658	1.18	0.1343	5	0.8210	1.12	0.0973	
	OW:BW	5	0.3423	R REF	0.0082	5	0.4050	1.18	0.0548	5	0.3911	1.14	0.0394	
	OW:BRN	5	0.3994	R REF	0.0297	5	0.4670	1.17	0.0981	5	0.4454	1.12	0.0555	
Kidney	ABS	5	1.5292	R REF	0.1580	5	1.6488	1.08	0.1319	5	1.7140	1.12	0.0779	
	OW:BW	5	0.7153	R REF	0.0451	5	0.7724	1.08	0.0504	5	0.8195	1.15	0.0738	*
	OW:BRN	5	0.8336	R REF	0.0651	5	0.8852	1.06	0.1104	5	0.9293	1.11	0.0428	
Liver	ABS	5	5.5626	R REF	0.4283	5	5.8068	1.04	0.3353	5	5.8276	1.05	0.5596	
	OW:BW	5	2.6032	R REF	0.0159	5	2.7204	1.05	0.1009	5	2.7738	1.07	0.1572	
	OW:BRN	5	3.0386	R REF	0.2392	5	3.1198	1.03	0.3699	5	3.1619	1.04	0.3341	
Ovary	ABS	5	0.1242	R REF	0.0347	5	0.1304	1.05	0.0384	5	0.1318	1.06	0.0253	
	OW:BW	5	0.0575	R REF	0.0121	5	0.0615	1.07	0.0196	5	0.0625	1.09	0.0088	
	OW:BRN	5	0.0674	R REF	0.0169	5	0.0695	1.03	0.0198	5	0.0717	1.06	0.0151	
Spleen	ABS	5	0.4412	R REF	0.0967	5	0.4746	1.08	0.0375	5	0.4472	1.01	0.0825	
	OW:BW	5	0.2050	R REF	0.0315	5	0.2227	1.09	0.0197	5	0.2117	1.03	0.0273	
	OW:BRN	5	0.2400	R REF	0.0471	5	0.2541	1.06	0.0241	5	0.2428	1.01	0.0468	
Thymus	ABS	5	0.4278	R REF	0.0718	5	0.4378	1.02	0.0238	5	0.3922	0.92	0.0443	
	OW:BW	5	0.2002	R REF	0.0310	5	0.2053	1.03	0.0111	5	0.1863	0.93	0.0103	
	OW:BRN	5	0.2349	R REF	0.0477	5	0.2350	1.00	0.0246	5	0.2131	0.91	0.0282	

Table 10

Summary Report of Macroscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Animals that were examined and found to be normal are not included in this report and the number of animals examined reflects the total number of animals examined grossly;
- = Value not applicable.

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Table 10

Summary Report of Macroscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

	Male			Female		
Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
Animals Examined:	**10**	**10**	**10**	**10**	**10**	**10**
LIVER						
Abnormal surface	-	1	-	-	-	-
LUNG						
Abnormal color	1	1	-	-	-	-
LYMPH NODE, DRAINING						
Abnormal size	-	1	-	-	1	4
LYMPH NODE, INGUINAL						
Abnormal size	1	-	-	-	-	2
SITE, INJECTION						
Abnormal color	-	2	1	1	3	-
Abnormal consistency	-	2	2	-	4	7
SPLEEN						
Abnormal size	-	-	-	-	-	1

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Table 10

Summary Report of Macroscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

	Male			Female		
Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
Animals Examined:	**5**	**5**	**5**	**5**	**5**	**5**
LYMPH NODE, DRAINING						
Abnormal size	-	1	-	-	-	1
LYMPH NODE, INGUINAL						
Abnormal size	-	-	-	-	-	1
ADIPOSE TISSUE						
Abnormal color	1	-	-	-	1	-
Abnormal consistency	1	-	-	-	-	-

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Table 11

Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

NOS= Not otherwise specified; - = Value not applicable.

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Table 11

Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
ARTERY, AORTA	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
BONE MARROW, STERNUM	Number Examined	10	10	10	10	10	10
	Unremarkable	10	0	0	10	0	0
Increased cellularity		-	10	10	-	10	10
	Minimal	-	10	10	-	10	10
BONE, STERNUM	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
BRAIN	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
CERVIX	Number Examined	-	-	-	10	10	10
	Unremarkable	-	-	-	10	10	10
EPIDIDYMIS	Number Examined	10	10	10	-	-	-
	Unremarkable	10	10	10	-	-	-
ESOPHAGUS	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
EYE	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	9	9	8
Mineralization, Cornea		-	-	-	-	1	-
	Minimal	-	-	-	-	1	-
Rosettes retina		-	-	-	1	-	2
	Minimal	-	-	-	1	-	2
GLAND, ADRENAL	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	9
Hypertrophy, Cortex		-	-	-	-	-	1
	Present	-	-	-	-	-	1
GLAND, HARDERIAN	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	6	9	7
Degeneration/Necrosis		-	-	-	2	-	2
	Minimal	-	-	-	2	-	2
Infiltration mononuclear cell		-	-	-	3	1	1
	Minimal	-	-	-	3	1	1
GLAND, LACRIMAL, EXTRAORBITAL	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
GLAND, MAMMARY	Number Examined	10	9	10	10	9	10
	Unremarkable	10	9	10	10	9	10

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
GLAND, PARATHYROID	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
GLAND, PITUITARY	Number Examined	10	10	10	10	10	10
	Unremarkable	10	9	8	9	10	8
Cyst		-	1	2	1	-	2
	Minimal	-	1	2	1	-	2
GLAND, PROSTATE	Number Examined	10	10	10	-	-	-
	Unremarkable	10	10	9	-	-	-
Infiltration mononuclear cell		-	-	1	-	-	-
	Minimal	-	-	1	-	-	-
GLAND, SALIVARY	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	9	10	10
Hypertrophy		-	-	-	1	-	-
	Minimal	-	-	-	1	-	-
GLAND, SEMINAL VESICLE	Number Examined	10	10	10	-	-	-
	Unremarkable	10	10	10	-	-	-
GLAND, THYROID	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
GUT-ASSOCIATED LYMPHOID TISSUE	Number Examined	10	10	10	8	10	10
	Unremarkable	10	10	10	8	9	10
Mineralization, Germinal center		-	-	-	-	1	-
	Minimal	-	-	-	-	1	-
HEART	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
JOINT	Number Examined	10	10	10	10	10	10
	Unremarkable	10	7	10	9	8	7
Inflammation, Extra-capsular		-	3	-	-	2	3
	Minimal	-	3	-	-	2	3
Physeal dysplasia		-	-	-	1	-	-
	Minimal	-	-	-	1	-	-
KIDNEY	Number Examined	10	10	10	10	10	10
	Unremarkable	9	9	9	8	6	10
Tubular basophilia		-	1	-	-	1	-
	Minimal	-	1	-	-	1	-
Infiltration mononuclear cell		-	-	1	2	3	-
	Minimal	-	-	1	2	3	-
Dilatation, Pelvis		1	-	-	-	-	-
	Minimal	1	-	-	-	-	-

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Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
LARGE INTESTINE, CECUM	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
LARGE INTESTINE, COLON	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	9
Infiltration mixed cell, Mucosa		-	-	-	-	-	1
	Minimal	-	-	-	-	-	1
LIVER	Number Examined	10	10	10	10	10	10
	Unremarkable	10	5	3	10	0	3
Vacuolation, Hepatocyte; Periportal		-	5	7	-	10	7
	Minimal	-	5	7	-	10	7
LUNG	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	9	9	10
Infiltration mixed cell		-	-	-	1	1	-
	Minimal	-	-	-	1	1	-

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Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
LYMPH NODE, DRAINING	Number Examined	10	9	10	10	10	10
	Unremarkable	8	1	1	8	1	1
Increased cellularity, Plasma cell		-	7	8	-	9	7
	Minimal	-	1	4	-	1	1
	Mild	-	4	3	-	1	5
	Moderate	-	2	1	-	7	1
Increased cellularity, Germinal center		2	6	8	2	5	6
	Minimal	1	2	2	1	3	4
	Mild	1	4	6	1	2	2
LYMPH NODE, INGUINAL	Number Examined	9	10	10	10	10	10
	Unremarkable	8	5	4	9	4	1
Increased cellularity, Germinal center		1	5	6	1	6	9
	Minimal	-	1	1	1	3	6
	Mild	1	4	5	-	3	3
Increased cellularity, Plasma cell		-	1	1	-	2	4
	Minimal	-	1	1	-	2	4
LYMPH NODE, MESENTERIC	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
MUSCLE, SKELETAL	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
NERVE, OPTIC	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
NERVE, PERIPHERAL	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
OVARY	Number Examined	-	-	-	10	10	10
	Unremarkable	-	-	-	10	10	10
OVIDUCT	Number Examined	-	-	-	10	10	10
	Unremarkable	-	-	-	10	10	10
PANCREAS	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	6	10
Atrophy, Acinar cell		-	-	-	-	4	-
	Minimal	-	-	-	-	4	-
Infiltration mononuclear cell, Interstitium		-	-	-	-	1	-
	Minimal	-	-	-	-	1	-

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
SITE, INJECTION	Number Examined	10	10	10	10	10	10
	Unremarkable	6	0	0	5	0	0
Inflammation		4	10	10	5	10	10
	Minimal	4	-	-	5	-	-
	Mild	-	7	5	-	7	9
	Moderate	-	3	5	-	3	1
Edema		-	9	9	-	10	10
	Mild	-	8	8	-	9	9
	Moderate	-	1	1	-	1	1
SKIN	Number Examined	10	10	10	10	9	10
	Unremarkable	10	10	10	10	9	10
SMALL INTESTINE, DUODENUM	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
SMALL INTESTINE, ILEUM	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
SMALL INTESTINE, JEJUNUM	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
SPINAL CORD	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
SPLEEN	Number Examined	10	10	10	10	10	10
	Unremarkable	10	0	0	10	0	0
Increased cellularity, Germinal center		-	5	5	-	6	5
	Minimal	-	5	5	-	6	5
Increased cellularity, Hematopoietic cell		-	10	10	-	9	10
	Minimal	-	10	10	-	9	10
STOMACH	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	9	10	9	10
Infiltration mononuclear cell, Serosa		-	-	-	-	1	-
	Minimal	-	-	-	-	1	-
Erosion		-	-	1	-	-	-
	Minimal	-	-	1	-	-	-
TESTIS	Number Examined	10	10	10	-	-	-
	Unremarkable	10	10	10	-	-	-
THYMUS	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
TONGUE	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10

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Study Phase: Dosing, Necropsy Status: Terminal Euthanasia

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**10**	**10**	**10**	**10**	**10**	**10**
TRACHEA	Number Examined	10	10	10	10	10	10
	Unremarkable	10	10	10	10	10	10
URETER	Number Examined	10	9	10	10	10	10
	Unremarkable	10	9	10	10	10	10
URINARY BLADDER	Number Examined	10	10	10	9	10	10
	Unremarkable	10	10	10	9	10	10
UTERUS	Number Examined	-	-	-	10	10	10
	Unremarkable	-	-	-	10	10	10
VAGINA	Number Examined	-	-	-	10	10	10
	Unremarkable	-	-	-	10	10	10
ADIPOSE TISSUE	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

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Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
ARTERY, AORTA	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
BONE MARROW, STERNUM	Number Examined	5	5	5	5	5	5
	Unremarkable	5	5	5	5	5	5
BONE, STERNUM	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
BRAIN	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
CERVIX	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
EPIDIDYMIS	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
ESOPHAGUS	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
EYE	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

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Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
GLAND, ADRENAL	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, HARDERIAN	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, LACRIMAL, EXTRAORBITAL	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, MAMMARY	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, PARATHYROID	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, PITUITARY	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, PROSTATE	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, SALIVARY	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

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Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
GLAND, SEMINAL VESICLE	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GLAND, THYROID	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
GUT-ASSOCIATED LYMPHOID TISSUE	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
HEART	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
JOINT	Number Examined	5	5	5	5	5	5
	Unremarkable	5	5	5	5	4	4
Physeal dysplasia		-	-	-	-	1	1
	Minimal	-	-	-	-	1	1
KIDNEY	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
LARGE INTESTINE, CECUM	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
LARGE INTESTINE, COLON	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

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Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
LIVER	Number Examined	5	5	5	5	5	5
	Unremarkable	5	5	5	5	5	5
LUNG	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
LYMPH NODE, DRAINING	Number Examined	4	5	5	5	5	5
	Unremarkable	4	0	0	4	0	0
Increased cellularity, Plasma cell		-	4	5	-	4	3
	Minimal	-	4	5	-	4	3
Increased cellularity, Germinal center		-	4	4	1	3	5
	Minimal	-	3	2	1	2	4
	Mild	-	1	2	-	1	1
Infiltration, Macrophage		-	3	4	-	3	4
	Minimal	-	2	2	-	1	1
	Mild	-	1	2	-	2	3

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
LYMPH NODE, INGUINAL	Number Examined	5	5	5	5	5	5
	Unremarkable	3	2	3	3	4	2
Increased cellularity, Germinal center		2	3	2	2	1	3
	Minimal	2	3	2	2	1	3
Increased cellularity, Plasma cell		-	-	-	-	-	1
	Minimal	-	-	-	-	-	1
Infiltration, Macrophage		-	-	1	-	-	1
	Minimal	-	-	1	-	-	1
LYMPH NODE, MESENTERIC	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
MUSCLE, SKELETAL	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
NERVE, OPTIC	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
NERVE, PERIPHERAL	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
OVARY	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

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Table 11

Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
OVIDUCT	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
PANCREAS	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
SITE, INJECTION	Number Examined	5	5	5	5	5	5
	Unremarkable	5	0	0	5	0	0
Inflammation		-	5	5	-	5	5
	Minimal	-	5	5	-	5	5
SKIN	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
SMALL INTESTINE, DUODENUM	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
SMALL INTESTINE, ILEUM	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
SMALL INTESTINE, JEJUNUM	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
SPINAL CORD	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

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Table 11

Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
SPLEEN	Number Examined	5	5	5	5	5	5
	Unremarkable	5	4	4	5	3	3
Increased cellularity, Germinal center		-	1	1	-	2	2
	Minimal	-	1	1	-	2	2
STOMACH	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
TESTIS	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
THYMUS	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
TONGUE	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
TRACHEA	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
URETER	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
URINARY BLADDER	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-

Table 11

Summary Report of Microscopic Observations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study Phase: Recovery, Necropsy Status: Recovery Euthanasia 1

		Male			Female		
	Group Number:	**1**	**2**	**3**	**1**	**2**	**3**
	Dose:	**0 µg/day**	**30 µg/day**	**30 µg /day**	**0 µg/day**	**30 µg/day**	**30 µg /day**
	No. Animals Per Dose Group:	**5**	**5**	**5**	**5**	**5**	**5**
UTERUS	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
VAGINA	Number Examined	-	-	-	-	-	-
	Unremarkable	-	-	-	-	-	-
ADIPOSE TISSUE	Number Examined	1	-	-	-	1	-
	Unremarkable	0	-	-	-	0	-
Inflammation		1	-	-	-	-	-
	Mild	1	-	-	-	-	-
Fibrosis		1	-	-	-	-	-
	Minimal	1	-	-	-	-	-
Infiltration mononuclear cell		-	-	-	-	1	-
	Mild	-	-	-	-	1	-

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20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Parameter	Phase	Day	Group	N	Mean	Standard Deviation	Pairwise p-value
Edema - Left	Dosing	1	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.63	0.51	0.001 **
			3: BNT162b3c	15	0.80	0.55	0.001 **
	Dosing	8	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	1.19	0.51	0.001 **
			3: BNT162b3c	15	1.43	0.12	0.001 **
	Dosing	15	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	1.33	0.45	0.001 **
			3: BNT162b3c	15	1.54	0.46	0.001 **

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Injection Site Score

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Parameter	Phase	Day	Group	N	Mean	Standard Deviation	Pairwise p-value
Erythema - Left	Dosing	1	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.03	0.13	0.682
			3: BNT162b3c	15	0.04	0.13	0.270
	Dosing	8	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.23	0.27	0.001 **
			3: BNT162b3c	15	0.41	0.17	0.001 **
	Dosing	15	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.00	0.00	0.999
			3: BNT162b3c	15	0.09	0.20	0.050 *

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Injection Site Score

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Parameter	Phase	Day	Group	N	Mean	Standard Deviation	Pairwise p-value
Edema - Left	Dosing	1	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	1.28	0.57	0.001 **
			3: BNT162b3c	15	1.08	0.58	0.001 **
	Dosing	8	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	1.44	0.23	0.001 **
			3: BNT162b3c	15	1.47	0.28	0.001 **
	Dosing	15	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	1.64	0.34	0.001 **
			3: BNT162b3c	15	1.78	0.27	0.001 **

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Injection Site Score

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Parameter	Phase	Day	Group	N	Mean	Standard Deviation	Pairwise p-value
Erythema - Left	Dosing	1	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.56	0.38	0.001 **
			3: BNT162b3c	15	0.66	0.17	0.001 **
	Dosing	8	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.50	0.09	0.001 **
			3: BNT162b3c	15	0.58	0.11	0.001 **
	Dosing	15	1: Saline	15	0.00	0.00	REF
			2: BNT162b2 (V9)	15	0.33	0.22	0.001 **
			3: BNT162b3c	15	0.60	0.14	0.001 **

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Injection Site Score

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Parameter	Phase	Group	N	Mean	Standard Deviation
Edema - Left	Recovery	2: BNT162b2 (V9)	4	1.08	0.17
		3: BNT162b3c	5	0.80	0.18
Erythema - Left	Recovery	2: BNT162b2 (V9)	4	0.00	0.00
		3: BNT162b3c	5	0.00	0.00

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Injection Site Score

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Parameter	Phase	Group	N	Mean	Standard Deviation
Edema - Left	Recovery	2: BNT162b2 (V9)	5	1.07	0.15
		3: BNT162b3c	5	1.13	0.18
Erythema - Left	Recovery	2: BNT162b2 (V9)	5	0.13	0.18
		3: BNT162b3c	5	0.33	0.24

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Body Temperature (Deg C)

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Phase	Day	Group	N	Mean	Standard Deviation	Pairwise p-value
Dosing	1	1: Saline	15	38.31	0.35	REF
		2: BNT162b2 (V9)	15	38.85	0.36	0.001 **
		3: BNT162b3c	15	39.02	0.40	0.001 **
Dosing	8	1: Saline	15	37.07	0.37	REF
		2: BNT162b2 (V9)	15	38.05	0.62	0.001 **
		3: BNT162b3c	15	38.33	0.43	0.001 **
Dosing	15	1: Saline	15	37.34	0.35	REF
		2: BNT162b2 (V9)	15	38.37	0.42	0.001 **
		3: BNT162b3c	15	38.43	0.36	0.001 **

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Body Temperature (Deg C)

20GR142: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Phase	Day	Group	N	Mean	Standard Deviation	Pairwise p-value
Dosing	1	1: Saline	15	38.08	0.44	REF
		2: BNT162b2 (V9)	15	38.50	0.53	0.044 *
		3: BNT162b3c	15	38.58	0.36	0.009 **
Dosing	8	1: Saline	15	37.81	0.38	REF
		2: BNT162b2 (V9)	15	38.47	0.44	0.001 **
		3: BNT162b3c	15	38.73	0.40	0.001 **
Dosing	15	1: Saline	15	38.02	0.74	REF
		2: BNT162b2 (V9)	15	38.15	0.54	0.963
		3: BNT162b3c	15	38.35	0.31	0.174

REF: Denotes group used as reference in the statistical tests.
* Statistically significant at 0.05 level ** Statistically significant at 0.01 level

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
001	M	1	1677	22 Jul 2020 08:53:06 AM	Dosing	17	22 Jul 2020 08:53:07 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
002	M	1	1787	22 Jul 2020 08:50:04 AM	Dosing	17	22 Jul 2020 08:50:05 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
003	M	1	727	22 Jul 2020 08:57:39 AM	Dosing	17	22 Jul 2020 08:57:40 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
004	M	1	598	22 Jul 2020 09:02:59 AM	Dosing	17	22 Jul 2020 09:02:59 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
005	M	1	727	22 Jul 2020 09:37:05 AM	Dosing	17	22 Jul 2020 09:37:06 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
006	M	1	1687	22 Jul 2020 09:46:22 AM	Dosing	17	22 Jul 2020 09:46:22 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
007	M	1	807	22 Jul 2020 09:58:31 AM	Dosing	17	22 Jul 2020 09:58:32 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
008	M	1	727	22 Jul 2020 10:17:27 AM	Dosing	17	22 Jul 2020 10:17:28 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
009	M	1	808	22 Jul 2020 10:30:03 AM	Dosing	17	22 Jul 2020 10:30:04 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
010	M	1	1777	22 Jul 2020 10:41:36 AM	Dosing	17	22 Jul 2020 10:41:36 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
011	M	1	1057	13 Aug 2020 07:32:04 AM	Recovery	22	13 Aug 2020 07:32:05 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
012	M	1	232	13 Aug 2020 08:15:17 AM	Recovery	22	13 Aug 2020 08:15:18 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
013	M	1	1307	13 Aug 2020 08:29:36 AM	Recovery	22	13 Aug 2020 08:29:37 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
014	M	1	1777	13 Aug 2020 09:02:02 AM	Recovery	22	13 Aug 2020 09:02:03 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
015	M	1	232	13 Aug 2020 09:23:27 AM	Recovery	22	13 Aug 2020 09:23:28 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
016	M	2	1057	22 Jul 2020 08:42:46 AM	Dosing	17	22 Jul 2020 08:42:47 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
017	M	2	1777	22 Jul 2020 08:48:01 AM	Dosing	17	22 Jul 2020 08:48:01 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
018	M	2	1307	22 Jul 2020 09:01:59 AM	Dosing	17	22 Jul 2020 09:01:59 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
019	M	2	807	22 Jul 2020 09:08:39 AM	Dosing	17	22 Jul 2020 09:08:39 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
020	M	2	1677	22 Jul 2020 09:41:57 AM	Dosing	17	22 Jul 2020 09:41:57 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
021	M	2	1308	22 Jul 2020 09:53:57 AM	Dosing	17	22 Jul 2020 09:53:58 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
022	M	2	598	22 Jul 2020 09:59:56 AM	Dosing	17	22 Jul 2020 09:59:56 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
023	M	2	1787	22 Jul 2020 10:29:38 AM	Dosing	17	22 Jul 2020 10:29:38 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
024	M	2	1307	22 Jul 2020 10:38:09 AM	Dosing	17	22 Jul 2020 10:38:10 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
025	M	2	807	22 Jul 2020 10:44:39 AM	Dosing	17	22 Jul 2020 10:44:40 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
026	M	2	1777	13 Aug 2020 07:36:45 AM	Recovery	22	13 Aug 2020 07:36:46 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
027	M	2	598	13 Aug 2020 08:25:28 AM	Recovery	22	13 Aug 2020 08:25:29 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
028	M	2	807	13 Aug 2020 08:44:11 AM	Recovery	22	13 Aug 2020 08:44:12 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
029	M	2	1057	13 Aug 2020 09:12:59 AM	Recovery	22	13 Aug 2020 09:13:00 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
030	M	2	598	13 Aug 2020 09:25:22 AM	Recovery	22	13 Aug 2020 09:25:24 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
031	M	3	1308	22 Jul 2020 08:47:19 AM	Dosing	17	22 Jul 2020 08:47:19 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
032	M	3	1687	22 Jul 2020 08:55:08 AM	Dosing	17	22 Jul 2020 08:55:08 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
033	M	3	808	22 Jul 2020 09:03:00 AM	Dosing	17	22 Jul 2020 09:03:01 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			

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Dead Animal Status Report

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
034	M	3	1057	22 Jul 2020 09:25:56 AM	Dosing	17	22 Jul 2020 09:25:56 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
035	M	3	808	22 Jul 2020 09:45:48 AM	Dosing	17	22 Jul 2020 09:45:49 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
036	M	3	1307	22 Jul 2020 09:56:54 AM	Dosing	17	22 Jul 2020 09:56:55 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
037	M	3	1057	22 Jul 2020 10:14:20 AM	Dosing	17	22 Jul 2020 10:14:21 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
038	M	3	1677	22 Jul 2020 10:27:35 AM	Dosing	17	22 Jul 2020 10:27:36 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
039	M	3	1687	22 Jul 2020 10:38:42 AM	Dosing	17	22 Jul 2020 10:38:43 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
040	M	3	598	22 Jul 2020 10:52:34 AM	Dosing	17	22 Jul 2020 10:52:35 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
041	M	3	808	13 Aug 2020 08:12:59 AM	Recovery	22	13 Aug 2020 08:13:00 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
042	M	3	1057	13 Aug 2020 08:26:36 AM	Recovery	22	13 Aug 2020 08:26:36 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
043	M	3	808	13 Aug 2020 08:59:12 AM	Recovery	22	13 Aug 2020 08:59:13 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
044	M	3	1307	13 Aug 2020 09:10:48 AM	Recovery	22	13 Aug 2020 09:10:49 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
045	M	3	807	13 Aug 2020 09:30:28 AM	Recovery	22	13 Aug 2020 09:30:29 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
046	F	1	727	22 Jul 2020 10:55:54 AM	Dosing	17	22 Jul 2020 10:55:55 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
047	F	1	808	22 Jul 2020 11:13:53 AM	Dosing	17	22 Jul 2020 11:13:53 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
048	F	1	1307	22 Jul 2020 11:32:53 AM	Dosing	17	22 Jul 2020 11:32:54 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
049	F	1	1777	22 Jul 2020 11:53:48 AM	Dosing	17	22 Jul 2020 11:53:48 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
050	F	1	1307	22 Jul 2020 12:09:56 PM	Dosing	17	22 Jul 2020 12:09:57 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
051	F	1	807	22 Jul 2020 12:17:24 PM	Dosing	17	22 Jul 2020 12:17:24 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
052	F	1	1677	22 Jul 2020 12:29:39 PM	Dosing	17	22 Jul 2020 12:29:39 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
053	F	1	1057	22 Jul 2020 12:41:24 PM	Dosing	17	22 Jul 2020 12:41:24 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
054	F	1	1308	22 Jul 2020 01:06:59 PM	Dosing	17	22 Jul 2020 01:06:59 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
055	F	1	1677	22 Jul 2020 01:13:05 PM	Dosing	17	22 Jul 2020 01:13:06 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			

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Dead Animal Status Report

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
056	F	1	808	13 Aug 2020 09:40:42 AM	Recovery	22	13 Aug 2020 09:40:43 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
057	F	1	1777	13 Aug 2020 10:06:54 AM	Recovery	22	13 Aug 2020 10:06:55 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
058	F	1	808	13 Aug 2020 10:24:39 AM	Recovery	22	13 Aug 2020 10:24:40 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
059	F	1	1307	13 Aug 2020 10:37:40 AM	Recovery	22	13 Aug 2020 10:37:41 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
060	F	1	598	13 Aug 2020 11:11:42 AM	Recovery	22	13 Aug 2020 11:11:43 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
061	F	2	1057	22 Jul 2020 10:59:29 AM	Dosing	17	22 Jul 2020 10:59:30 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
062	F	2	1687	22 Jul 2020 11:28:12 AM	Dosing	17	22 Jul 2020 11:28:13 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
063	F	2	807	22 Jul 2020 11:34:48 AM	Dosing	17	22 Jul 2020 11:34:48 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
064	F	2	808	22 Jul 2020 12:02:00 PM	Dosing	17	22 Jul 2020 12:02:01 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
065	F	2	1308	22 Jul 2020 12:10:34 PM	Dosing	17	22 Jul 2020 12:10:35 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
066	F	2	598	22 Jul 2020 12:26:23 PM	Dosing	17	22 Jul 2020 12:26:24 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
067	F	2	808	22 Jul 2020 12:39:45 PM	Dosing	17	22 Jul 2020 12:39:46 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
068	F	2	1307	22 Jul 2020 12:48:19 PM	Dosing	17	22 Jul 2020 12:48:20 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
069	F	2	1687	22 Jul 2020 01:10:04 PM	Dosing	17	22 Jul 2020 01:10:05 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
070	F	2	598	22 Jul 2020 01:20:52 PM	Dosing	17	22 Jul 2020 01:20:53 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
071	F	2	1307	13 Aug 2020 09:45:17 AM	Recovery	22	13 Aug 2020 09:45:18 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
072	F	2	807	13 Aug 2020 10:10:49 AM	Recovery	22	13 Aug 2020 10:10:51 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
073	F	2	232	13 Aug 2020 10:31:30 AM	Recovery	22	13 Aug 2020 10:31:32 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
074	F	2	807	13 Aug 2020 10:57:42 AM	Recovery	22	13 Aug 2020 10:57:44 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
075	F	2	1057	13 Aug 2020 11:14:34 AM	Recovery	22	13 Aug 2020 11:14:35 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
076	F	3	1308	22 Jul 2020 11:01:58 AM	Dosing	17	22 Jul 2020 11:01:59 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
077	F	3	727	22 Jul 2020 11:34:04 AM	Dosing	17	22 Jul 2020 11:34:04 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
078	F	3	1057	22 Jul 2020 11:39:37 AM	Dosing	17	22 Jul 2020 11:39:38 AM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
079	F	3	727	22 Jul 2020 12:04:24 PM	Dosing	17	22 Jul 2020 12:04:26 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
080	F	3	1787	22 Jul 2020 12:15:12 PM	Dosing	17	22 Jul 2020 12:15:13 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
081	F	3	1687	22 Jul 2020 12:23:21 PM	Dosing	17	22 Jul 2020 12:23:22 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
082	F	3	727	22 Jul 2020 12:40:34 PM	Dosing	17	22 Jul 2020 12:40:35 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
083	F	3	807	22 Jul 2020 01:00:12 PM	Dosing	17	22 Jul 2020 01:00:12 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
084	F	3	1777	22 Jul 2020 01:15:45 PM	Dosing	17	22 Jul 2020 01:15:45 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
085	F	3	727	22 Jul 2020 01:18:09 PM	Dosing	17	22 Jul 2020 01:18:10 PM	Y
Death Status: Terminal Euthanasia					**Death Type:** Scheduled			
086	F	3	1057	13 Aug 2020 09:54:23 AM	Recovery	22	13 Aug 2020 09:54:24 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
087	F	3	598	13 Aug 2020 10:20:29 AM	Recovery	22	13 Aug 2020 10:20:29 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
088	F	3	1057	13 Aug 2020 10:34:13 AM	Recovery	22	13 Aug 2020 10:34:14 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			

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Dead Animal Status Report

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StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Animal #	Sex	Group	User #	Date/Time Entered	Phase Name	Day of Phase	Date/Time of Death	Approx
089	F	3	1777	13 Aug 2020 11:07:56 AM	Recovery	22	13 Aug 2020 11:07:57 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
090	F	3	808	13 Aug 2020 11:19:57 AM	Recovery	22	13 Aug 2020 11:19:58 AM	Y
Death Status: Recovery Euthanasia 1					**Death Type:** Scheduled			
P-054#	F	-	1077	01 Jul 2020 01:57:34 PM	PID	8	01 Jul 2020 01:57:15 PM	Y
Death Status: Found Dead					**Death Type:** Unscheduled Death			
Comment: Died after blood collection								

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Dead Animal Status Report Audit Trail

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

No Audit Trail

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Appendix 2

Clinical Signs - Daily

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Animals were considered normal (data not displayed in table) unless indicated otherwise.
Note: Each interval will be concatenated with the phase name abbreviation.

- Value not applicable

Day(s) Observed - PID Prior to Initiation of Dosing, D Dosing, R Recovery

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Appendix 2

Clinical Signs - Daily

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
1	0 µg/day	012	Thin Appearance		D8	1
2	30 µg/day	024	Hair Loss	Abdomen, Thinning	D8, 15	2
		029	Tail Crooked		PID1-12, D1-17, R1-22	51

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Appendix 2

Clinical Signs - Daily

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
2	30 µg/day	067	Hair Loss	Forelimb, Bilateral, Thinning	D15	1
3	30 µg /day	083	Lesion	Lumbar, Dorsal	D1	1

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Note: Animals were considered normal (data not displayed in table) unless indicated otherwise.
Note: Each interval will be concatenated with the phase name abbreviation.

- Value not applicable

Day(s) Observed - PID	Prior to Initiation of Dosing, D	Dosing, R	Recovery

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
1	0 µg/day	001	No Ocular Abnormality	Bilateral	PID7, D15	2
		002	No Ocular Abnormality	Bilateral	PID7, D15	2
		003	No Ocular Abnormality	Bilateral	PID7, D15	2
		004	No Ocular Abnormality	Bilateral	PID7, D15	2
		005	No Ocular Abnormality	Bilateral	PID7, D15	2
		006	No Ocular Abnormality	Bilateral	PID7, D15	2
		007	No Ocular Abnormality	Bilateral	PID7, D15	2
		008	Vitreous, Hemorrhage	Mild, Left, Temporal, Ventral	PID7, D15	2
		009	No Ocular Abnormality	Bilateral	PID7, D15	2
		010	Retina, Tortuous Vessels	Minimal, Left, Generalized, Multifocal	PID7, D15	2
		011	Vitreous, Hyaloid Remnant	Minimal, Right, Central, Central	PID7, D15	2
		012	No Ocular Abnormality	Bilateral	PID7, D15	2
		013	No Ocular Abnormality	Bilateral	PID7, D15	2
		014	Keratic Precipitates	Mild, Left, Equatorial	PID7, D15	2
		015	No Ocular Abnormality	Bilateral	PID7, D15	2
2	30 µg/day	016	No Ocular Abnormality	Bilateral	PID7, D15	2
		017	No Ocular Abnormality	Bilateral	PID7, D15	2
		018	No Ocular Abnormality	Bilateral	PID7, D15	2

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
2	30 µg/day	019	No Ocular Abnormality	Bilateral	PID7, D15	2
		020	No Ocular Abnormality	Bilateral	PID7, D15	2
		021	No Ocular Abnormality	Bilateral	PID7, D15	2
		022	No Ocular Abnormality	Bilateral	PID7, D15	2
		023	No Ocular Abnormality	Bilateral	PID7, D15	2
		024	No Ocular Abnormality	Bilateral	PID7, D15	2
		025	No Ocular Abnormality	Bilateral	PID7, D15	2
		026	No Ocular Abnormality	Bilateral	PID7, D15	2
		027	No Ocular Abnormality	Bilateral	PID7, D15	2
		028	No Ocular Abnormality	Bilateral	PID7, D15	2
		029	No Ocular Abnormality	Bilateral	PID7, D15	2
		030	No Ocular Abnormality	Bilateral	PID7, D15	2
3	30 µg /day	031	No Ocular Abnormality	Bilateral	PID7, D15	2
		032	No Ocular Abnormality	Bilateral	PID7, D15	2
		033	No Ocular Abnormality	Bilateral	PID7, D15	2
		034	No Ocular Abnormality	Bilateral	PID7, D15	2
		035	No Ocular Abnormality	Bilateral	PID7, D15	2
		036	No Ocular Abnormality	Bilateral	PID7, D15	2
		037	No Ocular Abnormality	Bilateral	PID7, D15	2

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
3	30 µg /day	038	No Ocular Abnormality	Bilateral	PID7, D15	2
		039	No Ocular Abnormality	Bilateral	PID7, D15	2
		040	No Ocular Abnormality	Bilateral	PID7, D15	2
		041	Keratic Precipitates	Mild, Right, Equatorial	PID7, D15	2
		042	No Ocular Abnormality	Bilateral	PID7, D15	2
		043	No Ocular Abnormality	Bilateral	PID7, D15	2
		044	No Ocular Abnormality	Bilateral	PID7, D15	2
		045	No Ocular Abnormality	Bilateral	PID7, D15	2

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
1	0 µg/day	046	No Ocular Abnormality	Bilateral	PID8, D16	2
		047	No Ocular Abnormality	Bilateral	PID8, D16	2
		048	No Ocular Abnormality	Bilateral	PID8, D16	2
		049	Keratic Precipitates	Mild, Left, Equatorial	D16	1
			No Ocular Abnormality	Bilateral	PID8	1
		050	No Ocular Abnormality	Bilateral	PID8, D16	2
		051	No Ocular Abnormality	Bilateral	PID8, D16	2
		052	No Ocular Abnormality	Bilateral	PID8, D16	2
		053	No Ocular Abnormality	Bilateral	PID8, D16	2
		054	No Ocular Abnormality	Bilateral	PID8, D16	2
		055	No Ocular Abnormality	Bilateral	PID8, D16	2
		056	No Ocular Abnormality	Bilateral	PID8, D16	2
		057	No Ocular Abnormality	Bilateral	PID8, D16	2
		058	No Ocular Abnormality	Bilateral	PID8, D16	2
		059	No Ocular Abnormality	Bilateral	PID8, D16	2
		060	No Ocular Abnormality	Bilateral	PID8, D16	2
2	30 µg/day	061	No Ocular Abnormality	Bilateral	PID8, D16	2
		062	No Ocular Abnormality	Bilateral	PID8, D16	2
		063	No Ocular Abnormality	Bilateral	PID8, D16	2

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
2	30 µg/day	064	No Ocular Abnormality	Bilateral	PID8, D16	2
		065	No Ocular Abnormality	Bilateral	PID8, D16	2
		066	No Ocular Abnormality	Bilateral	PID8, D16	2
		067	No Ocular Abnormality	Bilateral	PID8, D16	2
		068	No Ocular Abnormality	Bilateral	PID8, D16	2
		069	No Ocular Abnormality	Bilateral	PID8, D16	2
		070	No Ocular Abnormality	Bilateral	PID8, D16	2
		071	No Ocular Abnormality	Bilateral	PID8, D16	2
		072	No Ocular Abnormality	Bilateral	PID8, D16	2
		073	No Ocular Abnormality	Bilateral	PID8, D16	2
		074	No Ocular Abnormality	Bilateral	PID8, D16	2
		075	No Ocular Abnormality	Bilateral	PID8, D16	2
3	30 µg /day	076	No Ocular Abnormality	Bilateral	PID8, D16	2
		077	No Ocular Abnormality	Bilateral	PID8, D16	2
		078	No Ocular Abnormality	Bilateral	PID8, D16	2
		079	No Ocular Abnormality	Bilateral	PID8, D16	2
		080	No Ocular Abnormality	Bilateral	PID8, D16	2
		081	No Ocular Abnormality	Bilateral	PID8, D16	2
		082	No Ocular Abnormality	Bilateral	PID8, D16	2

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Appendix 3

Ocular Exam

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Observations	Modifier	Day(s) Observed	Total Days Seen
3	30 µg /day	083	No Ocular Abnormality	Bilateral	PID8, D16	2
		084	No Ocular Abnormality	Bilateral	PID8, D16	2
		085	No Ocular Abnormality	Bilateral	PID8, D16	2
		086	No Ocular Abnormality	Bilateral	PID8, D16	2
		087	No Ocular Abnormality	Bilateral	PID8, D16	2
		088	No Ocular Abnormality	Bilateral	PID9, D16	2
		089	No Ocular Abnormality	Bilateral	PID8, D16	2
		090	No Ocular Abnormality	Bilateral	PID8, D16	2

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Grp Num = Group Number; Animal Num= Animal Number; - = Value not applicable; NW = Not Weighed; e = Excluded.
PID = Prior to the Initiation of Dosing.

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Day:	PID		Dosing					Recovery
				1	6	1	4	8	11	15	1
1	0 µg/day	001		178.3	217.8	252.9	239.1	270.5	284.3	290.1	-
		002		198.5	242.8	283.8	271.6	307.6	321.9	339.6	-
		003		180.0	226.4	270.2	259.1	291.0	306.8	318.6	-
		004		183.2	217.4	265.1	258.3	303.8	312.2	333.9	-
		005		185.6	223.1	263.8	254.0	286.4	301.4	315.8	-
		006		179.9	221.6	266.5	256.3	293.7	305.5	321.7	-
		007		195.6	232.1	270.8	259.9	295.6	310.2	321.8	-
		008		201.9	233.3	271.0	257.5	289.2	298.7	311.9	-
		009		178.5	210.0	248.2	240.6	267.4	276.0	293.1	-
		010		185.8	225.4	262.5	248.3	281.7	292.1	309.1	-
		011		195.6	227.8	264.1	257.1	291.2	296.8	310.2	313.8
		012		200.1	239.3	280.0	245.9	200.9	264.6	296.6	307.4
		013		183.6	213.9	243.1	233.1	262.7	268.5	283.4	287.6
		014		178.6	214.6	251.1	237.2	268.9	281.5	290.2	288.9
		015		190.5	233.7	278.9	264.4	298.4	317.0	336.1	340.8
2	30 µg/day	016		199.1	231.5	262.6	237.4	274.1	270.5	289.2	-
		017		182.0	218.3	266.9	249.5	291.2	292.1	307.0	-
		018		186.8	227.1	267.1	253.9	283.3	283.7	298.2	-
		019		193.4	233.0	269.3	258.6	287.4	292.6	309.8	-
		020		178.1	216.7	253.1	230.2	265.7	261.6	276.3	-
		021		185.4	228.6	269.4	248.9	279.2	276.5	296.0	-
		022		193.3	235.0	265.8	243.9	276.6	276.2	298.3	-
		023		184.6	222.6	259.9	241.4	273.0	281.2	296.1	-
		024		175.1	213.4	257.4	234.4	267.7	261.0	275.4	-
		025		200.1	239.9	284.6	268.0	311.6	307.9	325.5	-
		026		192.2	231.0	274.9	249.7	293.8	298.6	317.7	310.9
		027		186.8	222.2	265.8	243.4	286.4	284.0	306.3	306.0
		028		194.4	224.6	262.6	244.2	276.7	275.1	299.5	290.0
		029		195.7	239.4	280.0	259.6	295.1	297.4	320.4	312.8

Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Day:	PID		Dosing					Recovery
				1	6	1	4	8	11	15	1
2	30 µg/day	030		179.2	215.5	268.3	251.0	292.4	297.3	322.3	322.8
3	30 µg /day	031		191.0	216.0	244.2	224.5	250.4	250.3	268.7	-
		032		178.1	210.7	254.6	234.7	264.1	258.3	274.4	-
		033		194.1	236.2	291.6	269.8	310.8	315.8	330.5	-
		034		187.5	222.4	259.6	233.8	267.7	264.5	280.4	-
		035		188.1	227.2	256.5	227.2	259.4	245.6	267.8	-
		036		195.0	239.8	274.1	254.1	288.9	287.8	308.0	-
		037		192.8	235.5	275.8	249.6	293.7	290.9	313.1	-
		038		187.6	223.9	256.2	236.1	267.4	268.3	285.9	-
		039		187.9	224.4	264.2	239.6	281.4	274.0	292.6	-
		040		177.5	216.5	255.9	240.4	271.1	268.0	293.1	-
		041		197.7	231.3	270.2	262.3	290.2	290.9	303.5	300.9
		042		187.4	228.6	259.5	243.0	269.5	273.4	290.9	289.7
		043		195.2	232.1	273.3	252.9	280.3	285.3	306.7	302.6
		044		183.6	229.0	266.9	243.7	287.0	285.6	299.3	304.1
		045		177.0	214.1	249.3	226.4	262.5	260.0	284.4	282.3

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Day:	Recovery 4	8	11	15	18	21
1	0 µg/day	001		-	-	-	-	-	-
		002		-	-	-	-	-	-
		003		-	-	-	-	-	-
		004		-	-	-	-	-	-
		005		-	-	-	-	-	-
		006		-	-	-	-	-	-
		007		-	-	-	-	-	-
		008		-	-	-	-	-	-
		009		-	-	-	-	-	-
		010		-	-	-	-	-	-
		011		320.0	328.2	331.7	328.6	333.4	341.3
		012		326.5	346.5	349.9	359.0	373.6	381.6
		013		291.7	297.5	303.2	308.8	314.5	317.1
		014		291.5	297.3	298.6	297.3	302.0	304.7
		015		350.7	363.2	370.3	374.3	383.6	394.7
2	30 µg/day	016		-	-	-	-	-	-
		017		-	-	-	-	-	-
		018		-	-	-	-	-	-
		019		-	-	-	-	-	-
		020		-	-	-	-	-	-
		021		-	-	-	-	-	-
		022		-	-	-	-	-	-
		023		-	-	-	-	-	-
		024		-	-	-	-	-	-
		025		-	-	-	-	-	-
		026		326.6	336.1	345.8	354.4	362.2	369.9
		027		312.9	327.4	335.6	344.3	347.4	359.0
		028		303.3	310.9	331.8	335.2	341.1	344.1
		029		323.2	337.7	350.5	355.5	361.9	371.9

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Day:	Recovery 4	8	11	15	18	21
2	30 µg/day	030		337.6	352.3	369.0	383.8	384.8	403.1
3	30 µg /day	031		-	-	-	-	-	-
		032		-	-	-	-	-	-
		033		-	-	-	-	-	-
		034		-	-	-	-	-	-
		035		-	-	-	-	-	-
		036		-	-	-	-	-	-
		037		-	-	-	-	-	-
		038		-	-	-	-	-	-
		039		-	-	-	-	-	-
		040		-	-	-	-	-	-
		041		312.3	327.1	331.7	340.8	351.0	357.8
		042		299.5	311.4	320.1	328.4	336.8	344.2
		043		313.6	331.7	336.5	344.4	355.5	362.5
		044		311.9	324.6	333.6	344.6	351.3	366.3
		045		293.5	308.8	316.1	315.8	326.1	340.4

Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Day:	PID		Dosing					Recovery
				1	6	1	4	8	11	15	1
1	0 µg/day	046		151.3	169.9	188.5	177.4	192.7	202.2	206.7	-
		047		164.8	183.0	195.7	194.1	227.9	235.3	233.7	-
		048		156.5	170.4	185.8	172.6	195.1	187.6	190.0	-
		049		155.4	173.4	192.9	179.6	204.3	201.8	208.1	-
		050		149.6	174.8	185.3	182.4	218.0	227.9	227.0	-
		051		167.5	185.7	201.8	191.8	214.4	206.7	209.3	-
		052		158.8	176.0	206.3	190.6	213.7	213.3	220.6	-
		053		157.6	177.5	199.6	187.7	207.1	212.2	215.4	-
		054		166.0	186.8	203.7	193.6	211.0	225.7	230.7	-
		055		155.8	174.8	191.2	178.0	203.0	206.4	211.2	-
		056		166.8	181.7	203.6	188.4	211.9	210.5	219.0	224.3
		057		149.4	164.5	184.1	168.4	187.6	197.3	199.7	199.4
		058		151.7	169.0	187.0	172.2	186.8	197.4	204.0	204.8
		059		151.3	168.4	186.9	176.3	205.7	208.1	215.4	212.2
		060		173.1	189.5	209.5	194.7	218.7	221.1	223.6	234.7
2	30 µg/day	061		163.9	180.5	202.1	181.3	209.9	210.3	229.7	-
		062		157.5	172.7	183.1	174.6	203.0	205.8	208.9	-
		063		160.0	171.0	186.2	178.0	197.2	195.8	201.9	-
		064		162.7	184.5	198.0	187.2	215.7	208.9	216.1	-
		065		157.2	182.6	188.7	173.3	199.0	207.9	219.0	-
		066		171.4	186.7	203.9	187.0	215.0	215.8	219.6	-
		067		156.8	168.5	192.0	182.3	207.4	208.7	217.5	-
		068		152.0	169.9	187.6	169.0	190.5	187.7	196.9	-
		069		163.9	181.5	197.2	177.4	200.3	213.1	232.7	-
		070		174.1	188.9	202.5	185.8	206.0	211.6	227.2	-
		071		167.1	175.4	180.3	171.3	195.0	202.6	212.3	205.5
		072		153.5	174.3	196.8	177.1	207.9	198.7	213.4	206.6
		073		146.6	163.7	176.7	168.0	190.9	195.5	198.3	203.7
		074		154.4	168.3	186.3	173.0	195.0	192.4	196.3	204.8

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Day:	PID		Dosing					Recovery
				1	6	1	4	8	11	15	1
2	30 µg/day	075		156.4	176.2	191.5	174.4	204.8	203.4	220.5	215.5
3	30 µg /day	076		169.2	176.6	204.0	186.9	204.0	209.1	215.5	-
		077		155.0	167.5	181.6	171.1	184.4	194.2	213.2	-
		078		158.2	182.3	207.2	181.9	217.2	208.4	231.7	-
		079		159.0	175.8	194.7	175.2	191.4	206.9	227.1	-
		080		159.3	181.9	195.2	184.6	216.0	220.7	223.6	-
		081		158.6	168.4	192.4	178.0	194.7	201.5	208.6	-
		082		148.7	162.1	187.5	177.1	196.6	192.1	204.4	-
		083		154.1	166.2	187.3	175.1	197.5	204.6	207.0	-
		084		165.1	188.8	200.6	184.3	213.6	210.8	217.8	-
		085		159.2	174.0	189.3	168.8	187.3	193.9	199.1	-
		086		154.4	173.5	180.3	166.1	183.6	192.9	207.6	213.3
		087		162.2	180.8	198.4	182.2	204.0	215.8	241.3	242.5
		088		150.5	159.0	172.9	161.5	180.3	176.1	182.5	180.6
		089		170.6	185.8	204.4	184.1	211.3	209.9	218.4	208.1
		090		169.5	191.4	194.4	177.1	201.8	205.6	211.1	215.1

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Day:	Recovery 4	8	11	15	18	21
1	0 µg/day	046		-	-	-	-	-	-
		047		-	-	-	-	-	-
		048		-	-	-	-	-	-
		049		-	-	-	-	-	-
		050		-	-	-	-	-	-
		051		-	-	-	-	-	-
		052		-	-	-	-	-	-
		053		-	-	-	-	-	-
		054		-	-	-	-	-	-
		055		-	-	-	-	-	-
		056		234.4	243.0	241.5	238.7	238.8	246.9
		057		198.4	207.9	212.2	211.5	210.8	218.3
		058		207.6	210.0	204.5	213.9	211.2	219.1
		059		209.4	209.7	218.0	217.0	221.5	218.0
		060		235.9	249.5	243.9	240.1	245.4	242.0
2	30 µg/day	061		-	-	-	-	-	-
		062		-	-	-	-	-	-
		063		-	-	-	-	-	-
		064		-	-	-	-	-	-
		065		-	-	-	-	-	-
		066		-	-	-	-	-	-
		067		-	-	-	-	-	-
		068		-	-	-	-	-	-
		069		-	-	-	-	-	-
		070		-	-	-	-	-	-
		071		212.7	221.2	226.2	218.8	225.0	235.6
		072		217.4	227.3	224.6	225.6	224.6	242.1
		073		200.9	207.9	210.8	213.6	215.3	215.5
		074		219.4	221.2	217.4	217.4	222.8	226.7

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Appendix 4

Body Weight (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Day:	Recovery 4	8	11	15	18	21
2	30 µg/day	075		214.6	223.1	228.5	227.5	235.1	236.7
3	30 µg /day	076		-	-	-	-	-	-
		077		-	-	-	-	-	-
		078		-	-	-	-	-	-
		079		-	-	-	-	-	-
		080		-	-	-	-	-	-
		081		-	-	-	-	-	-
		082		-	-	-	-	-	-
		083		-	-	-	-	-	-
		084		-	-	-	-	-	-
		085		-	-	-	-	-	-
		086		207.2	209.8	215.1	221.0	228.4	220.1
		087		235.5	239.1	233.2	241.0	252.5	246.1
		088		188.7	194.7	192.5	188.4	194.3	197.3
		089		217.4	225.8	226.0	222.2	229.6	234.3
		090		223.1	230.0	224.3	213.9	221.1	224.5

Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Grp Num = Group Number; Animal Num = Animal Number; - = Value not applicable; NW = Not Weighed; e = Excluded.

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Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Days:	PID	Dosing					Recovery	
				1-6	1-4	4-8	8-11	11-15	1-15	1-4	4-8
1	0 µg/day	001		39.5	-13.8	31.4	13.8	5.8	37.2	-	-
		002		44.3	-12.2	36.0	14.3	17.7	55.8	-	-
		003		46.4	-11.1	31.9	15.8	11.8	48.4	-	-
		004		34.2	-6.8	45.5	8.4	21.7	68.8	-	-
		005		37.5	-9.8	32.4	15.0	14.4	52.0	-	-
		006		41.7	-10.2	37.4	11.8	16.2	55.2	-	-
		007		36.5	-10.9	35.7	14.6	11.6	51.0	-	-
		008		31.4	-13.5	31.7	9.5	13.2	40.9	-	-
		009		31.5	-7.6	26.8	8.6	17.1	44.9	-	-
		010		39.6	-14.2	33.4	10.4	17.0	46.6	-	-
		011		32.2	-7.0	34.1	5.6	13.4	46.1	6.2	8.2
		012		39.2	-34.1	-45.0	63.7	32.0	16.6	19.1	20.0
		013		30.3	-10.0	29.6	5.8	14.9	40.3	4.1	5.8
		014		36.0	-13.9	31.7	12.6	8.7	39.1	2.6	5.8
		015		43.2	-14.5	34.0	18.6	19.1	57.2	9.9	12.5
2	30 µg/day	016		32.4	-25.2	36.7	-3.6	18.7	26.6	-	-
		017		36.3	-17.4	41.7	0.9	14.9	40.1	-	-
		018		40.3	-13.2	29.4	0.4	14.5	31.1	-	-
		019		39.6	-10.7	28.8	5.2	17.2	40.5	-	-
		020		38.6	-22.9	35.5	-4.1	14.7	23.2	-	-
		021		43.2	-20.5	30.3	-2.7	19.5	26.6	-	-
		022		41.7	-21.9	32.7	-0.4	22.1	32.5	-	-
		023		38.0	-18.5	31.6	8.2	14.9	36.2	-	-
		024		38.3	-23.0	33.3	-6.7	14.4	18.0	-	-
		025		39.8	-16.6	43.6	-3.7	17.6	40.9	-	-
		026		38.8	-25.2	44.1	4.8	19.1	42.8	15.7	9.5
		027		35.4	-22.4	43.0	-2.4	22.3	40.5	6.9	14.5
		028		30.2	-18.4	32.5	-1.6	24.4	36.9	13.3	7.6

Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Days:	PID 1-6	Dosing 1-4	Dosing 4-8	Dosing 8-11	Dosing 11-15	Dosing 1-15	Recovery 1-4	Recovery 4-8
2	30 µg/day	029		43.7	-20.4	35.5	2.3	23.0	40.4	10.4	14.5
		030		36.3	-17.3	41.4	4.9	25.0	54.0	14.8	14.7
3	30 µg /day	031		25.0	-19.7	25.9	-0.1	18.4	24.5	-	-
		032		32.6	-19.9	29.4	-5.8	16.1	19.8	-	-
		033		42.1	-21.8	41.0	5.0	14.7	38.9	-	-
		034		34.9	-25.8	33.9	-3.2	15.9	20.8	-	-
		035		39.1	-29.3	32.2	-13.8	22.2	11.3	-	-
		036		44.8	-20.0	34.8	-1.1	20.2	33.9	-	-
		037		42.7	-26.2	44.1	-2.8	22.2	37.3	-	-
		038		36.3	-20.1	31.3	0.9	17.6	29.7	-	-
		039		36.5	-24.6	41.8	-7.4	18.6	28.4	-	-
		040		39.0	-15.5	30.7	-3.1	25.1	37.2	-	-
		041		33.6	-7.9	27.9	0.7	12.6	33.3	11.4	14.8
		042		41.2	-16.5	26.5	3.9	17.5	31.4	9.8	11.9
		043		36.9	-20.4	27.4	5.0	21.4	33.4	11.0	18.1
		044		45.4	-23.2	43.3	-1.4	13.7	32.4	7.8	12.7
		045		37.1	-22.9	36.1	-2.5	24.4	35.1	11.2	15.3

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Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase Days:	Recovery 8-11	11-15	15-18	18-21	1-21
1	0 µg/day	001		-	-	-	-	-
		002		-	-	-	-	-
		003		-	-	-	-	-
		004		-	-	-	-	-
		005		-	-	-	-	-
		006		-	-	-	-	-
		007		-	-	-	-	-
		008		-	-	-	-	-
		009		-	-	-	-	-
		010		-	-	-	-	-
		011		3.5	-3.1	4.8	7.9	27.5
		012		3.4	9.1	14.6	8.0	74.2
		013		5.7	5.6	5.7	2.6	29.5
		014		1.3	-1.3	4.7	2.7	15.8
		015		7.1	4.0	9.3	11.1	53.9
2	30 µg/day	016		-	-	-	-	-
		017		-	-	-	-	-
		018		-	-	-	-	-
		019		-	-	-	-	-
		020		-	-	-	-	-
		021		-	-	-	-	-
		022		-	-	-	-	-
		023		-	-	-	-	-
		024		-	-	-	-	-
		025		-	-	-	-	-
		026		9.7	8.6	7.8	7.7	59.0
		027		8.2	8.7	3.1	11.6	53.0
		028		20.9	3.4	5.9	3.0	54.1

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Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase	Recovery				
			Days:	8-11	11-15	15-18	18-21	1-21
2	30 µg/day	029		12.8	5.0	6.4	10.0	59.1
		030		16.7	14.8	1.0	18.3	80.3
3	30 µg /day	031		-	-	-	-	-
		032		-	-	-	-	-
		033		-	-	-	-	-
		034		-	-	-	-	-
		035		-	-	-	-	-
		036		-	-	-	-	-
		037		-	-	-	-	-
		038		-	-	-	-	-
		039		-	-	-	-	-
		040		-	-	-	-	-
		041		4.6	9.1	10.2	6.8	56.9
		042		8.7	8.3	8.4	7.4	54.5
		043		4.8	7.9	11.1	7.0	59.9
		044		9.0	11.0	6.7	15.0	62.2
		045		7.3	-0.3	10.3	14.3	58.1

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Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Days:	PID	Dosing					Recovery	
				1-6	1-4	4-8	8-11	11-15	1-15	1-4	4-8
1	0 µg/day	046		18.6	-11.1	15.3	9.5	4.5	18.2	-	-
		047		18.2	-1.6	33.8	7.4	-1.6	38.0	-	-
		048		13.9	-13.2	22.5	-7.5	2.4	4.2	-	-
		049		18.0	-13.3	24.7	-2.5	6.3	15.2	-	-
		050		25.2	-2.9	35.6	9.9	-0.9	41.7	-	-
		051		18.2	-10.0	22.6	-7.7	2.6	7.5	-	-
		052		17.2	-15.7	23.1	-0.4	7.3	14.3	-	-
		053		19.9	-11.9	19.4	5.1	3.2	15.8	-	-
		054		20.8	-10.1	17.4	14.7	5.0	27.0	-	-
		055		19.0	-13.2	25.0	3.4	4.8	20.0	-	-
		056		14.9	-15.2	23.5	-1.4	8.5	15.4	10.1	8.6
		057		15.1	-15.7	19.2	9.7	2.4	15.6	-1.0	9.5
		058		17.3	-14.8	14.6	10.6	6.6	17.0	2.8	2.4
		059		17.1	-10.6	29.4	2.4	7.3	28.5	-2.8	0.3
		060		16.4	-14.8	24.0	2.4	2.5	14.1	1.2	13.6
2	30 µg/day	061		16.6	-20.8	28.6	0.4	19.4	27.6	-	-
		062		15.2	-8.5	28.4	2.8	3.1	25.8	-	-
		063		11.0	-8.2	19.2	-1.4	6.1	15.7	-	-
		064		21.8	-10.8	28.5	-6.8	7.2	18.1	-	-
		065		25.4	-15.4	25.7	8.9	11.1	30.3	-	-
		066		15.3	-16.9	28.0	0.8	3.8	15.7	-	-
		067		11.7	-9.7	25.1	1.3	8.8	25.5	-	-
		068		17.9	-18.6	21.5	-2.8	9.2	9.3	-	-
		069		17.6	-19.8	22.9	12.8	19.6	35.5	-	-
		070		14.8	-16.7	20.2	5.6	15.6	24.7	-	-
		071		8.3	-9.0	23.7	7.6	9.7	32.0	7.2	8.5
		072		20.8	-19.7	30.8	-9.2	14.7	16.6	10.8	9.9
		073		17.1	-8.7	22.9	4.6	2.8	21.6	-2.8	7.0

Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Days:	PID	Dosing					Recovery	
				1-6	1-4	4-8	8-11	11-15	1-15	1-4	4-8
2	30 µg/day	074		13.9	-13.3	22.0	-2.6	3.9	10.0	14.6	1.8
		075		19.8	-17.1	30.4	-1.4	17.1	29.0	-0.9	8.5
3	30 µg /day	076		7.4	-17.1	17.1	5.1	6.4	11.5	-	-
		077		12.5	-10.5	13.3	9.8	19.0	31.6	-	-
		078		24.1	-25.3	35.3	-8.8	23.3	24.5	-	-
		079		16.8	-19.5	16.2	15.5	20.2	32.4	-	-
		080		22.6	-10.6	31.4	4.7	2.9	28.4	-	-
		081		9.8	-14.4	16.7	6.8	7.1	16.2	-	-
		082		13.4	-10.4	19.5	-4.5	12.3	16.9	-	-
		083		12.1	-12.2	22.4	7.1	2.4	19.7	-	-
		084		23.7	-16.3	29.3	-2.8	7.0	17.2	-	-
		085		14.8	-20.5	18.5	6.6	5.2	9.8	-	-
		086		19.1	-14.2	17.5	9.3	14.7	27.3	-6.1	2.6
		087		18.6	-16.2	21.8	11.8	25.5	42.9	-7.0	3.6
		088		8.5	-11.4	18.8	-4.2	6.4	9.6	8.1	6.0
		089		15.2	-20.3	27.2	-1.4	8.5	14.0	9.3	8.4
		090		21.9	-17.3	24.7	3.8	5.5	16.7	8.0	6.9

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Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase Days:	Recovery 8-11	11-15	15-18	18-21	1-21
1	0 µg/day	046		-	-	-	-	-
		047		-	-	-	-	-
		048		-	-	-	-	-
		049		-	-	-	-	-
		050		-	-	-	-	-
		051		-	-	-	-	-
		052		-	-	-	-	-
		053		-	-	-	-	-
		054		-	-	-	-	-
		055		-	-	-	-	-
		056		-1.5	-2.8	0.1	8.1	22.6
		057		4.3	-0.7	-0.7	7.5	18.9
		058		-5.5	9.4	-2.7	7.9	14.3
		059		8.3	-1.0	4.5	-3.5	5.8
		060		-5.6	-3.8	5.3	-3.4	7.3
2	30 µg/day	061		-	-	-	-	-
		062		-	-	-	-	-
		063		-	-	-	-	-
		064		-	-	-	-	-
		065		-	-	-	-	-
		066		-	-	-	-	-
		067		-	-	-	-	-
		068		-	-	-	-	-
		069		-	-	-	-	-
		070		-	-	-	-	-
		071		5.0	-7.4	6.2	10.6	30.1
		072		-2.7	1.0	-1.0	17.5	35.5
		073		2.9	2.8	1.7	0.2	11.8

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Appendix 5

Body Weight Change During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase	Recovery				
			Days:	8-11	11-15	15-18	18-21	1-21
2	30 µg/day	074		-3.8	0.0	5.4	3.9	21.9
		075		5.4	-1.0	7.6	1.6	21.2
3	30 µg /day	076		-	-	-	-	-
		077		-	-	-	-	-
		078		-	-	-	-	-
		079		-	-	-	-	-
		080		-	-	-	-	-
		081		-	-	-	-	-
		082		-	-	-	-	-
		083		-	-	-	-	-
		084		-	-	-	-	-
		085		-	-	-	-	-
		086		5.3	5.9	7.4	-8.3	6.8
		087		-5.9	7.8	11.5	-6.4	3.6
		088		-2.2	-4.1	5.9	3.0	16.7
		089		0.2	-3.8	7.4	4.7	26.2
		090		-5.7	-10.4	7.2	3.4	9.4

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

Num = Number; - = Value not applicable; NW = Not Weighed; e = Excluded; SP = Spilled.

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase: Days:	Dosing					Recovery		
				1-4	4-8	8-11	11-15	1-15	1-4	4-8	8-11
1	0 µg/day	001		53.4	92.3	66.2	87.0	298.9	-	-	-
		002		53.5	100.9	66.5	92.1	313.0	-	-	-
		003		53.6	92.7	70.2	85.0	301.5	-	-	-
		004		51.8	106.3	66.5	96.8	321.4	-	-	-
		005		50.4	95.2	67.9	87.4	300.9	-	-	-
		006		54.3	100.3	62.6	95.1	312.3	-	-	-
		007		54.4	106.8	70.4	92.3	323.9	-	-	-
		008		45.3	89.9	64.8	84.1	284.1	-	-	-
		009		50.5	86.2	58.9	87.2	282.8	-	-	-
		010		46.8	88.5	67.6	87.4	290.3	-	-	-
		011		51.5	97.4	59.9	85.1	293.9	48.2	74.0	55.8
		012		39.7	18.5	58.5	101.2	217.9	56.2	97.1	63.2
		013		51.9	85.1	53.2	81.5	271.7	39.6	72.9	52.6
		014		53.3	95.8	69.8	84.2	303.1	44.4	75.5	52.0
		015		52.8	107.1	68.5	93.9	322.3	51.7	91.1	67.0
2	30 µg/day	016		35.5	85.3	47.2	81.5	249.5	-	-	-
		017		43.1	95.9	53.2	97.7	289.9	-	-	-
		018		46.1	101.9	57.4	88.9	294.3	-	-	-
		019		45.0	92.8	49.2	86.1	273.1	-	-	-
		020		40.7	91.7	47.0	84.9	264.3	-	-	-
		021		34.4	89.8	46.4	91.1	261.7	-	-	-

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Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase: Days:	Dosing					Recovery		
				1-4	4-8	8-11	11-15	1-15	1-4	4-8	8-11
2	30 µg/day	022		41.2	90.7	49.3	84.6	265.8	-	-	-
		023		42.2	89.0	54.1	84.2	269.5	-	-	-
		024		38.6	90.5	51.2	86.2	266.5	-	-	-
		025		51.1	114.3	61.9	104.3	331.6	-	-	-
		026		43.6	101.5	65.9	101.9	312.9	63.9	94.9	65.3
		027		46.4	101.0	57.0	90.9	295.3	62.8	89.6	63.3
		028		41.9	90.8	50.7	92.3	275.7	61.3	84.0	66.5
		029		45.7	107.5	57.2	97.8	308.2	65.6	90.9	68.2
		030		43.4	108.6	62.6	110.9	325.5	70.1	105.2	76.7
3	30 µg /day	031		33.4	75.7	45.2	74.5	228.8	-	-	-
		032		40.9	85.0	41.1	86.8	253.8	-	-	-
		033		36.3	116.5	63.6	100.2	316.6	-	-	-
		034		36.3	84.9	47.1	80.6	248.9	-	-	-
		035		33.4	80.0	35.7	80.5	229.6	-	-	-
		036		42.4	87.4	55.1	89.2	274.1	-	-	-
		037		39.4	105.8	56.7	103.3	305.2	-	-	-
		038		39.2	79.7	52.5	82.9	254.3	-	-	-
		039		33.8	97.4	49.6	87.1	267.9	-	-	-
		040		38.6	95.1	44.6	101.0	279.3	-	-	-
		041		53.9	105.4	61.5	93.1	313.9	70.0	94.5	67.3
		042		34.0	91.5	46.9	82.2	254.6	59.8	79.8	56.9

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase:	Dosing					Recovery		
			Days:	1-4	4-8	8-11	11-15	1-15	1-4	4-8	8-11
3	30 µg /day	043		39.6	78.2	50.6	86.5	254.9	58.4	83.2	61.6
		044		38.7	98.2	55.6	94.1	286.6	63.2	92.5	61.6
		045		40.4	89.8	50.9	90.0	271.1	59.9	83.2	66.1

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase: Days:	Recovery 11-15	15-18	18-21	1-21
1	0 µg/day	001		-	-	-	-
		002		-	-	-	-
		003		-	-	-	-
		004		-	-	-	-
		005		-	-	-	-
		006		-	-	-	-
		007		-	-	-	-
		008		-	-	-	-
		009		-	-	-	-
		010		-	-	-	-
		011		69.1	53.3	50.5	350.9
		012		87.6	68.2	66.9	439.2
		013		68.6	54.3	51.6	339.6
		014		70.9	53.6	56.9	353.3
		015		85.9	69.1	70.5	435.3
2	30 µg/day	016		-	-	-	-
		017		-	-	-	-
		018		-	-	-	-
		019		-	-	-	-
		020		-	-	-	-
		021		-	-	-	-

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Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase: Days:	Recovery 11-15	15-18	18-21	1-21
2	30 µg/day	022		-	-	-	-
		023		-	-	-	-
		024		-	-	-	-
		025		-	-	-	-
		026		87.1	68.5	67.9	447.6
		027		82.1	64.7	64.1	426.6
		028		75.1	59.3	63.9	410.1
		029		82.8	62.2	63.3	433.0
		030		96.5	67.6	73.0	489.1
3	30 µg /day	031		-	-	-	-
		032		-	-	-	-
		033		-	-	-	-
		034		-	-	-	-
		035		-	-	-	-
		036		-	-	-	-
		037		-	-	-	-
		038		-	-	-	-
		039		-	-	-	-
		040		-	-	-	-
		041		85.4	70.3	70.0	457.5
		042		71.6	58.4	53.6	380.1

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Grp Num	Dose	Animal Num	Phase: Days:	Recovery 11-15	15-18	18-21	1-21
3	30 µg /day	043		76.1	58.4	56.5	394.2
		044		85.8	65.0	69.8	437.9
		045		77.1	60.9	60.8	408.0

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Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase: Days:	Dosing					Recovery		
				1-4	4-8	8-11	11-15	1-15	1-4	4-8	8-11
1	0 µg/day	046		32.9	61.5	47.7	54.5	196.6	-	-	-
		047		41.0	87.3	61.3	77.0	266.6	-	-	-
		048		35.6	72.7	44.7	64.2	217.2	-	-	-
		049		36.3	72.0	43.4	63.5	215.2	-	-	-
		050		42.8	83.1	59.2	69.6	254.7	-	-	-
		051		37.5	67.9	42.3	67.2	214.9	-	-	-
		052		43.8	79.3	46.3	64.0	233.4	-	-	-
		053		39.1	74.0	47.1	61.9	222.1	-	-	-
		054		41.8	84.0	58.1	77.5	261.4	-	-	-
		055		35.1	68.4	46.2	59.1	208.8	-	-	-
		056		35.8	75.7	47.3	72.5	231.3	54.1	70.3	51.0
		057		28.2	64.0	39.5	55.0	186.7	43.2	62.4	45.0
		058		34.8	63.2	42.7	56.1	196.8	42.4	55.2	40.0
		059		40.2	81.0	44.7	65.8	231.7	45.2	56.7	45.7
		060		42.0	82.8	53.6	71.2	249.6	53.1	72.0	49.9
2	30 µg/day	061		30.3	74.3	44.2	80.6	229.4	-	-	-
		062		34.0	65.9	40.3	61.5	201.7	-	-	-
		063		36.7	70.6	38.7	66.5	212.5	-	-	-
		064		36.6	77.5	46.5	71.6	232.2	-	-	-
		065		23.9	72.6	42.7	66.2	205.4	-	-	-
		066		29.5	71.5	41.1	56.8	198.9	-	-	-

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase: Days:	Dosing					Recovery		
				1-4	4-8	8-11	11-15	1-15	1-4	4-8	8-11
2	30 µg/day	067		37.3	78.2	45.8	68.4	229.7	-	-	-
		068		30.0	59.8	37.7	56.7	184.2	-	-	-
		069		34.0	71.0	44.2	72.5	221.7	-	-	-
		070		32.9	70.8	41.7	71.7	217.1	-	-	-
		071		37.4	72.6	40.4	66.9	217.3	55.6	67.9	51.2
		072		34.0	71.0	38.4	66.1	209.5	47.7	68.7	47.1
		073		32.9	72.4	39.6	63.5	208.4	44.2	63.3	44.1
		074		31.4	67.3	40.0	58.1	196.8	54.2	63.8	41.9
		075		34.4	66.9	46.5	71.7	219.5	46.9	69.7	49.2
3	30 µg /day	076		38.5	76.7	50.1	70.3	235.6	-	-	-
		077		34.2	71.1	40.5	77.0	222.8	-	-	-
		078		25.5	74.6	36.2	72.1	208.4	-	-	-
		079		30.1	67.5	43.8	76.3	217.7	-	-	-
		080		37.3	82.4	55.1	74.3	249.1	-	-	-
		081		31.8	64.5	34.7	65.3	196.3	-	-	-
		082		31.7	66.9	37.4	62.8	198.8	-	-	-
		083		33.3	71.5	45.0	66.8	216.6	-	-	-
		084		78.1	75.9	39.0	62.1	255.1	-	-	-
		085		29.8	66.7	39.3	66.7	202.5	-	-	-
		086		27.3	64.9	36.4	62.6	191.2	47.8	60.3	42.8
		087		38.6	85.4	43.6	90.6	258.2	57.6	82.6	53.6

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase:	Dosing					Recovery		
			Days:	1-4	4-8	8-11	11-15	1-15	1-4	4-8	8-11
3	30 µg /day	088		26.7	65.5	31.8	54.8	178.8	45.4	62.4	38.3
		089		28.5	64.7	37.4	60.1	190.7	44.1	59.9	42.1
		090		28.1	77.6	36.0	65.7	207.4	50.2	69.2	36.8

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase: Days:	Recovery 11-15	15-18	18-21	1-21
1	0 µg/day	046		-	-	-	-
		047		-	-	-	-
		048		-	-	-	-
		049		-	-	-	-
		050		-	-	-	-
		051		-	-	-	-
		052		-	-	-	-
		053		-	-	-	-
		054		-	-	-	-
		055		-	-	-	-
		056		67.1	47.3	50.0	339.8
		057		56.2	39.3	46.0	292.1
		058		52.0	38.9	45.2	273.7
		059		52.6	36.9	38.6	275.7
		060		67.5	49.8	45.2	337.5
2	30 µg/day	061		-	-	-	-
		062		-	-	-	-
		063		-	-	-	-
		064		-	-	-	-
		065		-	-	-	-
		066		-	-	-	-

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase: Days:	Recovery 11-15	15-18	18-21	1-21
2	30 µg/day	067		-	-	-	-
		068		-	-	-	-
		069		-	-	-	-
		070		-	-	-	-
		071		58.4	46.1	48.6	327.8
		072		63.9	36.2	48.1	311.7
		073		55.4	40.2	41.1	288.3
		074		61.4	44.0	44.4	309.7
		075		65.8	51.7	51.8	335.1
3	30 µg /day	076		-	-	-	-
		077		-	-	-	-
		078		-	-	-	-
		079		-	-	-	-
		080		-	-	-	-
		081		-	-	-	-
		082		-	-	-	-
		083		-	-	-	-
		084		-	-	-	-
		085		-	-	-	-
		086		60.1	44.2	41.1	296.3
		087		77.3	57.0	55.9	384.0

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Appendix 6

Food Consumption - Empty Feeder During Interval (g)

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Grp Num	Dose	Animal Num	Phase: Days:	Recovery 11-15	15-18	18-21	1-21
3	30 µg /day	088		50.3	37.6	40.0	274.0
		089		52.8	41.5	42.6	283.0
		090		48.9	43.5	44.2	292.8

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Appendix 7

Hematology and Coagulation
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description	Parameter	Description
RBC	Red Blood Cells	BASO	Basophil, Absolute
HGB	Hemoglobin	BASO_P	Basophil
HCT	Hematocrit	LUC	Large Unstained Cells, Absolute
MCV	Mean Cell Volume	LUC_P	Large Unstained Cells
MCH	Mean Cell Hemoglobin	MORPH	Morphology
MCHC	Mean Cell Hemoglobin Conc	POIK	Poikilocytosis
RDW	Red Cell Distribution Width	BURR	Burr Cells
RETIC_P	Reticulocyte	SCHISTO	Schistocytes
RETIC	Reticulocyte, Absolute	SPHERO	Spherocytes
PLT	Platelets	SIDERO	Siderocyte-like Inclusions
MPV	Mean Platelet Volume	TARGET	Target Cells
WBC	White Blood Cells	TEAR	Tear Drop Cells
NEUT	Neutrophil, Absolute	B_STIP	Basophilic Stippling
NEUT_P	Neutrophil	HJ	Howell-Jolly Bodies
LYM	Lymphocyte, Absolute	AGGL	Agglutination
LYM_P	Lymphocyte	CLPLT	Clumped Platelets
MONO	Monocyte, Absolute	HGB_CRYS	Hemoglobin Crystals
MONO_P	Monocyte	BASOPH	Basophilia
EO	Eosinophil, Absolute	ACANTH	Acanthocytes
EO_P	Eosinophil	STOM	Stomatocytes

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Hematology and Coagulation
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description
OTHERM	Other Morphology
DOHLE	Dohle Bodies
HYSEG	Hypersegmented Neutrophils
TOXIC_G	Toxic Granulation
TOXIC_V	Toxic Vacuolation
VACLYM	Vacuolated Lymphocytes
PT_Rat	Prothrombin Time, Rat
APTT	Activated Partial Thromboplastin Time
FIB	Fibrinogen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Comment	Description
CE	Critical result for Subject # RatWis042 ; Time point R022 transmitted electronically to clinically responsible personnel.
CE	Critical result for Subject # RatWis044 ; Time point R022 transmitted electronically to clinically responsible personnel.
CL	Clotted
FT	Subject# Ratwis031; Timepoint D004; Lymphocytes
NS	No Sample
QN	Quantity Not Sufficient
RP	Clumped platelets on original result; sample redrawn and reported.
RR	Result repeated
RW	RDW and MCV not reportable due to abnormal cytogram
SR	Slide Reviewed

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

- Value not applicable;

Note: Each interval/day will be concatenated with the phase name abbreviation

HPD = Hours Post Dose; U = Unscheduled

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	RDW %
1	0 µg/day	001	4D	--	8.64	15.9	50.0	57.8	18.4	31.7	11.6
			17D	-	8.38	14.9	46.2	55.2	17.8	32.2	11.1
		002	4D	--	8.07	15.7	48.7	60.4	19.4	32.2	12.1
			17D	-	7.33	13.8	42.8	58.3	18.8	32.2	11.7
		003	4D	--	8.11	15.0	49.2	60.6	18.5	30.5	12.1
			17D	-	- CL	- CL	- CL	- CL	- CL	- CL	- CL
		004	4D	--	8.17	14.8	48.0	58.8	18.2	30.9	13.0
			17D	-	7.63	14.0	42.6	55.8	18.4	32.9	11.8
		005	4D	--	8.02	14.4	46.4	57.8	18.0	31.1	12.7
			17D	-	7.06	12.7	38.8	55.0	18.0	32.8	12.3
		006	4D	--	8.05	14.6	47.3	58.7	18.2	30.9	12.4
			17D	-	7.95	14.2	44.4	55.8	17.9	32.0	12.0
		007	4D	--	7.76	14.7	46.7	60.2	18.9	31.4	12.0
			17D	-	7.43	13.7	42.3	57.0	18.4	32.3	11.7
		008	17D	-	8.10	14.5	45.1	55.7	18.0	32.2	11.6
		009	17D	-	6.75	12.8	39.4	58.5	19.0	32.5	11.4
		010	17D	-	7.63	13.8	41.9	54.9	18.1	33.0	11.1

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL	HGB g/dL	HCT %	MCV fL		MCH pg	MCHC g/dL	RDW %	
1	0 µg/day	011	22R	-	7.29	12.8	37.9	52.1		17.6	33.8	12.2	
		012	22R	-	8.02	14.2	43.8	54.6		17.7	32.5	12.1	
		013	22R	-	8.61	15.5	46.4	-	RW	18.0	33.4	-	RW
		014	22R	-	8.06	15.0	43.6	54.2		18.6	34.4	11.3	
		015	22R	-	7.77	14.3	42.2	54.3		18.4	33.9	12.1	
2	30 µg/day	016	4D	--	8.30	15.0	46.2	55.7		18.1	32.5	11.9	
			17D	-	7.03	12.2	36.9	52.5		17.3	33.0	13.3	
		017	4D	--	7.60	13.4	41.4	54.5		17.6	32.3	13.1	
			17D	-	6.76	11.3	35.1	51.9		16.8	32.4	14.0	
		018	4D	--	7.71	13.9	42.0	54.5		18.0	33.1	13.8	
			17D	-	7.52	13.0	38.9	51.8		17.3	33.4	15.5	
		019	4D	--	7.56	14.1	43.4	57.4		18.7	32.6	12.4	
			17D	-	7.20	12.9	39.5	54.9		17.9	32.6	13.5	
		020	4D	--	7.92	14.0	43.3	54.7		17.7	32.4	12.9	
			17D	-	7.57	12.9	39.7	52.4		17.0	32.5	13.4	
		021	4D	--	7.43	13.7	42.4	57.0		18.4	32.3	13.5	
			17D	-	6.66	11.7	36.5	54.8		17.6	32.2	14.8	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL	HGB g/dL	HCT %	MCV fL		MCH pg	MCHC g/dL	RDW %	
2	30 µg/day	022	4D	--	7.90	15.0	44.9	56.9		18.9	33.3	12.2	
			17D	-	7.21	13.1	39.5	54.7		18.2	33.3	14.1	
		023	17D	-	7.35	12.4	39.0	53.1		16.9	31.7	14.3	
		024	17D	-	7.16	12.6	39.0	54.5		17.6	32.4	14.8	
		025	17D	-	7.23	13.2	39.9	55.2		18.2	33.0	13.5	
		026	22R	-	8.26	14.0	43.6	52.8		17.0	32.2	13.5	
		027	22R	-	8.35	15.0	46.0	55.2		17.9	32.5	13.5	
		028	22R	-	8.11	14.1	43.5	53.6		17.4	32.4	13.1	
		029	22R	-	7.87	14.6	43.5	-	RW	18.5	33.6	-	RW
		030	22R	-	7.73	14.2	42.0	54.4		18.4	33.8	13.8	
3	30 µg /day	031	4D	--	7.62	13.5	42.3	55.6		17.8	32.0	11.8	
			17D	-	6.93	11.9	36.9	53.2		17.2	32.3	12.9	
		032	4D	--	7.23	13.8	42.9	59.4		19.1	32.2	13.3	
			17D	-	7.02	12.6	39.6	56.5		17.9	31.8	14.1	
		033	4D	--	7.41	13.8	43.6	58.9		18.7	31.7	12.7	
			17D	-	7.40	13.3	41.9	56.6		17.9	31.7	13.9	
		034	4D	--	7.79	14.1	43.6	56.0		18.1	32.3	12.1	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL	HGB g/dL	HCT %	MCV fL		MCH pg	MCHC g/dL	RDW %	
3	30 µg /day	034	17D	-	7.42	13.0	39.7	53.5		17.5	32.8	13.6	
		035	4D	--	7.85	14.4	45.4	57.7		18.3	31.7	12.2	
			17D	-	7.34	13.2	40.1	54.7		18.0	33.0	13.9	
		036	4D	--	7.93	14.6	45.3	57.1		18.5	32.3	12.4	
			17D	-	7.46	13.3	40.6	54.4		17.8	32.6	13.2	
		037	4D	--	7.34	13.9	43.4	59.1		19.0	32.1	12.6	
			17D	-	6.88	12.5	38.8	56.5		18.1	32.1	13.6	
		038	17D	-	6.77	12.3	37.7	55.6		18.2	32.8	14.0	
		039	17D	-	7.37	13.3	39.7	53.9		18.0	33.4	14.4	
		040	17D	-	6.54	12.7	37.9	-	RW	19.5	33.6	-	RW
		041	22R	-	8.36	14.7	45.9	55.0		17.6	32.1	14.0	
		042	22R	-	7.62	13.8	42.5	55.7		18.1	32.5	13.1	
		043	22R	-	7.91	13.6	41.9	53.1		17.2	32.4	13.2	
		044	22R	-	8.22	14.2	43.9	53.4		17.3	32.3	13.0	
		045	22R	-	7.32	13.7	40.7	-	RW	18.8	33.7	-	RW

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RETIC_P %	RETIC 10^3/uL	PLT 10^3/uL	MPV fL	WBC 10e3/uL	NEUT 10^3/uL	NEUT_P %
1	0 µg/day	001	4D	--	4.6	397	1132	8.3	7.5	0.92	12.2
			17D	-	2.4	201	870	8.3	3.7	0.75	20.3
		002	4D	--	4.8	387	963	8.9	5.6	0.97	17.3
			17D	-	2.5	183	873	9.1	3.9	0.70	17.9
		003	4D	--	5.1	414	1154	9.1	7.4	0.58	7.8
			17D	-	- CL	- CL	- CL	- CL	- CL	- CL	- CL
		004	4D	--	5.5	449	1099	8.9	8.4	1.43	16.9
			17D	-	2.5	191	958	9.3	5.4	1.29	24.1
		005	4D	--	5.3	425	1069	8.5	8.8	0.68	7.7
			17D	-	2.7	191	927	9.1	1.9	0.18	9.4
		006	4D	--	4.8	386	1014	9.2	7.1	1.24	17.3
			17D	-	2.0	159	905	9.5	5.4	1.08	19.8
		007	4D	--	3.7	287	658	9.2	8.4	1.76	21.0
			17D	-	1.7	126	918	8.9	6.3	0.99	15.7
		008	17D	-	2.4	194	794	9.5	4.1	0.43	10.3
		009	17D	-	2.9	196	750	9.2	1.5	0.29	19.6
		010	17D	-	2.2	168	937	9.2	2.4	0.36	15.2

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RETIC_P %	RETIC 10^3/uL	PLT 10^3/uL	MPV fL	WBC 10e3/uL	NEUT 10^3/uL	NEUT_P %
1	0 µg/day	011	22R	-	2.5	182	909	9.2	2.2	0.60	27.6
		012	22R	-	2.8	225	834	9.2	4.9	0.93	19.1
		013	22R	-	2.1	181	865	8.8	9.5	1.49	15.7
		014	22R	-	1.8	145	809	8.7	4.6	0.56	12.1
		015	22R	-	2.2	171	822	9.1	5.1	0.91	17.9
2	30 µg/day	016	4D	--	1.3	108	910	9.9	13.0	2.97	22.8
			17D	-	2.9	204	564	10.6	6.4	3.27	50.8
		017	4D	--	0.7	53	1143	9.2	12.6	2.90	23.1
			17D	-	2.7	183	927	9.4	8.8	4.96	56.1
		018	4D	--	0.8	62	1044	9.5	14.3	2.83	19.8
			17D	-	2.0	150	815	9.4	14.5	6.56	45.1
		019	4D	--	2.4	181	1004	9.2	7.3	1.67	22.9
			17D	-	2.5	180	855	9.3	7.4	3.76	51.1
		020	4D	--	1.0	79	1177	8.9	12.0	3.24	27.0
			17D	-	2.2	167	880	9.0	12.8	7.32	57.0
		021	4D	--	1.6	119	1039	9.6	6.6	0.95	14.3
			17D	-	2.3	153	655	9.7	3.5	1.45	41.3

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RETIC_P %	RETIC 10^3/uL	PLT 10^3/uL		MPV fL		WBC 10e3/uL	NEUT 10^3/uL	NEUT_P %
2	30 µg/day	022	4D	--	1.9	150	961	RP	7.7	RP	9.1	2.73	30.1
			17D	-	2.5	180	926		9.8		9.4	4.80	50.8
		023	17D	-	2.6	191	872		9.3		4.0	1.86	46.9
		024	17D	-	3.0	215	724		9.9		9.6	4.94	51.5
		025	17D	-	3.2	231	795		9.1		11.9	5.57	46.7
		026	22R	-	2.7	223	816		8.7		4.3	1.19	27.7
		027	22R	-	2.2	184	910		8.9		6.4	1.14	17.8
		028	22R	-	2.7	219	769		9.1		5.5	0.69	12.5
		029	22R	-	1.9	150	1054		9.0		6.3	1.20	19.0
		030	22R	-	2.3	178	973		8.5		7.4	1.13	15.3
3	30 µg /day	031	4D	--	1.5	114	898		9.6		7.6	1.38	18.0
			17D	-	2.8	194	534	SR	10.1		6.7	3.36	49.9
		032	4D	--	1.5	108	937		10.3		11.1	2.60	23.5
			17D	-	2.9	204	807		10.1		10.5	5.08	48.3
		033	4D	--	1.0	74	1187		9.6		12.3	2.89	23.5
			17D	-	2.4	178	974		9.3		9.2	5.03	54.6
		034	4D	--	1.3	101	843		10.1		9.2	2.07	22.4

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Appendix 7

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	RETIC_P %	RETIC 10^3/uL	PLT 10^3/uL		MPV fL	WBC 10e3/uL	NEUT 10^3/uL	NEUT_P %
3	30 µg /day	034	17D	-	2.6	193	708		10.3	8.0	4.24	52.9
		035	4D	--	1.6	126	780		9.6	8.1	1.66	20.6
			17D	-	2.8	206	594	SR	10.5	7.8	3.76	48.2
		036	4D	--	1.8	143	1024		9.3	10.0	2.34	23.3
			17D	-	2.7	201	908		9.8	10.1	5.34	52.8
		037	4D	--	0.9	66	947		9.4	9.6	2.19	22.7
			17D	-	2.5	172	667		9.6	8.0	3.82	47.6
		038	17D	-	3.0	203	702		10.8	9.1	4.57	50.2
		039	17D	-	2.8	206	759		9.4	8.6	4.72	54.9
		040	17D	-	2.8	183	737		9.4	8.0	3.59	44.7
		041	22R	-	2.4	201	789		9.2	4.9	1.36	27.7
		042	22R	-	2.6	198	689		9.1	2.9	0.70	23.9
		043	22R	-	2.1	166	822		8.7	5.9	1.37	23.3
		044	22R	-	2.6	214	890		8.8	5.2	1.53	29.6
		045	22R	-	2.1	154	998		8.6	5.6	1.42	25.4

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL	LYM_P %	MONO 10^3/uL	MONO_P %	EO 10^3/uL	EO_P %	BASO 10^3/uL
1	0 µg/day	001	4D	--	6.35	84.4	0.12	1.5	0.07	0.9	0.02
			17D	-	2.80	75.4	0.03	0.9	0.09	2.6	0.00
		002	4D	--	4.46	79.1	0.12	2.2	0.03	0.6	0.01
			17D	-	3.00	76.9	0.13	3.2	0.04	1.0	0.00
		003	4D	--	6.60	89.3	0.11	1.5	0.06	0.8	0.01
			17D	-	- CL	- CL	- CL	- CL	- CL	- CL	- CL
		004	4D	--	6.80	80.6	0.09	1.0	0.06	0.7	0.01
			17D	-	3.85	71.8	0.12	2.3	0.06	1.1	0.01
		005	4D	--	7.86	89.2	0.12	1.4	0.08	0.9	0.02
			17D	-	1.66	87.1	0.03	1.5	0.03	1.3	0.00
		006	4D	--	5.64	79.2	0.13	1.8	0.06	0.8	0.02
			17D	-	4.12	75.6	0.11	2.1	0.09	1.7	0.01
		007	4D	--	6.28	74.9	0.07	0.8	0.21	2.5	0.02
			17D	-	5.09	81.2	0.08	1.2	0.06	1.0	0.01
		008	17D	-	3.53	85.4	0.08	2.0	0.06	1.5	0.00
		009	17D	-	1.14	77.0	0.03	2.2	0.02	1.1	0.00
		010	17D	-	1.89	80.7	0.03	1.4	0.05	1.9	0.00

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL	LYM_P %	MONO 10^3/uL	MONO_P %	EO 10^3/uL	EO_P %	BASO 10^3/uL
1	0 µg/day	011	22R	-	1.47	67.8	0.04	1.9	0.05	2.2	0.00
		012	22R	-	3.77	77.5	0.08	1.7	0.06	1.2	0.00
		013	22R	-	7.62	80.3	0.12	1.3	0.14	1.4	0.03
		014	22R	-	3.91	85.1	0.05	1.2	0.03	0.7	0.00
		015	22R	-	4.02	78.7	0.08	1.5	0.06	1.2	0.01
2	30 µg/day	016	4D	--	9.19	70.5	0.28	2.2	0.13	1.0	0.04
			17D	-	2.49	38.7	0.19	3.0	0.13	2.0	0.01
		017	4D	--	9.00	71.6	0.28	2.3	0.04	0.3	0.04
			17D	-	3.34	37.8	0.21	2.3	0.10	1.1	0.02
		018	4D	--	10.85	75.9	0.26	1.8	0.10	0.7	0.04
			17D	-	6.78	46.6	0.45	3.1	0.17	1.1	0.05
		019	4D	--	5.39	74.1	0.11	1.5	0.03	0.4	0.01
			17D	-	3.18	43.2	0.15	2.1	0.15	2.1	0.01
		020	4D	--	8.33	69.4	0.17	1.4	0.07	0.5	0.03
			17D	-	4.88	38.1	0.37	2.9	0.11	0.9	0.02
		021	4D	--	5.47	82.5	0.09	1.3	0.05	0.7	0.01
			17D	-	1.72	49.2	0.06	1.8	0.13	3.7	0.00

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL	LYM_P %	MONO 10^3/uL	MONO_P %	EO 10^3/uL	EO_P %	BASO 10^3/uL
2	30 µg/day	022	4D	--	5.86	64.7	0.20	2.2	0.18	2.0	0.04
			17D	-	4.11	43.5	0.25	2.7	0.17	1.8	0.02
		023	17D	-	1.84	46.5	0.14	3.5	0.06	1.4	0.01
		024	17D	-	4.03	42.0	0.17	1.8	0.26	2.7	0.01
		025	17D	-	5.55	46.5	0.35	2.9	0.13	1.0	0.02
		026	22R	-	2.93	68.5	0.09	2.2	0.04	1.0	0.00
		027	22R	-	4.98	78.0	0.11	1.7	0.09	1.5	0.01
		028	22R	-	4.61	83.7	0.08	1.5	0.06	1.2	0.01
		029	22R	-	4.85	76.9	0.12	1.9	0.08	1.3	0.01
		030	22R	-	5.99	80.6	0.13	1.8	0.10	1.4	0.01
3	30 µg /day	031	4D	--	5.57	72.9	0.19	2.5	0.07	0.9	0.03
			17D	-	2.82	41.9	0.11	1.6	0.12	1.7	0.01
		032	4D	--	8.07	72.9	0.22	2.0	0.05	0.4	0.04
			17D	-	4.68	44.5	0.33	3.2	0.14	1.3	0.02
		033	4D	--	8.85	72.0	0.24	1.9	0.07	0.5	0.05
			17D	-	3.41	36.9	0.29	3.2	0.09	1.0	0.02
		034	4D	--	6.69	72.3	0.21	2.3	0.09	1.0	0.03

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL	LYM_P %	MONO 10^3/uL	MONO_P %	EO 10^3/uL	EO_P %	BASO 10^3/uL
3	30 µg /day	034	17D	-	2.74	34.2	0.37	4.6	0.09	1.1	0.02
		035	4D	--	5.91	73.2	0.18	2.2	0.15	1.9	0.02
			17D	-	3.27	41.9	0.19	2.4	0.17	2.1	0.01
		036	4D	--	7.20	71.7	0.23	2.3	0.12	1.2	0.06
			17D	-	4.11	40.6	0.33	3.3	0.07	0.7	0.03
		037	4D	--	6.92	71.9	0.23	2.4	0.09	0.9	0.03
			17D	-	3.63	45.2	0.24	3.0	0.11	1.3	0.02
		038	17D	-	3.64	40.0	0.22	2.4	0.27	2.9	0.02
		039	17D	-	3.40	39.5	0.23	2.7	0.10	1.1	0.01
		040	17D	-	3.77	47.0	0.23	2.9	0.06	0.8	0.03
		041	22R	-	3.34	68.0	0.09	1.8	0.09	1.9	0.01
		042	22R	-	2.10	71.6	0.08	2.7	0.03	1.2	0.00
		043	22R	-	4.29	72.8	0.12	2.1	0.07	1.2	0.01
		044	22R	-	3.34	64.7	0.13	2.6	0.13	2.4	0.01
		045	22R	-	3.97	71.0	0.10	1.8	0.05	0.9	0.01

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	BASO_P %	LUC 10^3/uL	LUC_P %	MORPH none	POIK none	BURR none	SCHISTO none
1	0 µg/day	001	4D	--	0.3	0.06	0.7	-	-	-	-
			17D	-	0.1	0.03	0.7	Reported	-	-	-
		002	4D	--	0.1	0.04	0.7	-	-	-	-
			17D	-	0.0	0.03	0.8	Normal	-	-	-
		003	4D	--	0.1	0.03	0.4	-	-	-	-
			17D	-	- CL	- CL	- CL	- CL	-	-	-
		004	4D	--	0.2	0.05	0.6	-	-	-	-
			17D	-	0.1	0.04	0.7	Normal	-	-	-
		005	4D	--	0.3	0.06	0.7	-	-	-	-
			17D	-	0.0	0.01	0.6	Normal	-	-	-
		006	4D	--	0.3	0.04	0.6	-	-	-	-
			17D	-	0.2	0.03	0.5	Normal	-	-	-
		007	4D	--	0.3	0.04	0.5	-	-	-	-
			17D	-	0.2	0.04	0.7	-	-	-	-
		008	17D	-	0.0	0.03	0.7	-	-	-	-
		009	17D	-	0.1	0.00	0.1	-	-	-	-
		010	17D	-	0.1	0.02	0.6	-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	BASO_P %	LUC 10^3/uL	LUC_P %		MORPH none	POIK none	BURR none	SCHISTO none
1	0 µg/day	011	22R	-	0.2	0.01	0.3		Reported	-	Present	-
		012	22R	-	0.1	0.02	0.4		Reported	-	Present	-
		013	22R	-	0.3	0.08	0.9		Reported	-	Present	-
		014	22R	-	0.1	0.03	0.7		Normal	-	-	-
		015	22R	-	0.1	0.03	0.5		Normal	-	-	-
2	30 µg/day	016	4D	--	0.3	0.43	3.3		-	-	-	-
			17D	-	0.2	0.34	5.3	SR	Reported	-	-	-
		017	4D	--	0.4	0.30	2.4		-	-	-	-
			17D	-	0.2	0.22	2.5		Reported	-	-	-
		018	4D	--	0.3	0.21	1.5		-	-	-	-
			17D	-	0.3	0.53	3.7		Normal	-	-	-
		019	4D	--	0.2	0.07	0.9		-	-	-	-
			17D	-	0.2	0.10	1.3		Reported	-	-	-
		020	4D	--	0.3	0.17	1.4		-	-	-	-
			17D	-	0.2	0.13	1.0		Reported	-	-	-
		021	4D	--	0.2	0.07	1.1		-	-	-	-
			17D	-	0.1	0.13	3.8		-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	BASO_P %	LUC 10^3/uL	LUC_P %		MORPH none	POIK none	BURR none	SCHISTO none
2	30 µg/day	022	4D	--	0.4	0.06	0.6		-	-	-	-
			17D	-	0.2	0.10	1.1		-	-	-	-
		023	17D	-	0.1	0.06	1.6		-	-	-	-
		024	17D	-	0.1	0.17	1.8		-	-	-	-
		025	17D	-	0.2	0.31	2.6		-	-	-	-
		026	22R	-	0.1	0.03	0.7		Reported	-	Present	-
		027	22R	-	0.2	0.05	0.7		Reported	-	Present	-
		028	22R	-	0.2	0.05	0.9		Reported	-	Present	-
		029	22R	-	0.2	0.05	0.8		Normal	-	-	-
		030	22R	-	0.2	0.06	0.8		Normal	-	-	-
3	30 µg /day	031	4D	--	0.4	0.40	5.3	FT	-	-	-	-
			17D	-	0.2	0.31	4.7		Normal	-	-	-
		032	4D	--	0.4	0.09	0.8		-	-	-	-
			17D	-	0.2	0.25	2.4		Reported	-	-	-
		033	4D	--	0.4	0.20	1.7		-	-	-	-
			17D	-	0.2	0.38	4.1		-	-	-	-
		034	4D	--	0.3	0.16	1.7		-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	BASO_P %	LUC 10^3/uL	LUC_P %		MORPH none	POIK none	BURR none	SCHISTO none
3	30 µg /day	034	17D	-	0.2	0.56	7.0	SR	Reported	-	-	-
		035	4D	--	0.3	0.15	1.8		-	-	-	-
			17D	-	0.1	0.41	5.3	SR	Reported	-	-	-
		036	4D	--	0.6	0.10	0.9		-	-	-	-
			17D	-	0.3	0.24	2.3		-	-	-	-
		037	4D	--	0.3	0.18	1.8		-	-	-	-
			17D	-	0.3	0.21	2.6		-	-	-	-
		038	17D	-	0.2	0.38	4.2		-	-	-	-
		039	17D	-	0.1	0.15	1.7		-	-	-	-
		040	17D	-	0.3	0.34	4.3		Reported	-	Present	-
		041	22R	-	0.1	0.02	0.5		Reported	-	-	-
		042	22R	-	0.0	0.02	0.6		Reported	-	Present	-
		043	22R	-	0.1	0.02	0.4		Normal	-	-	-
		044	22R	-	0.1	0.03	0.6		Normal	-	-	-
		045	22R	-	0.1	0.04	0.7		Normal	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	SPHERO none	SIDERO none	TARGET none	TEAR none	B_STIP none	HJ none	AGGL none
1	0 µg/day	001	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		002	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		003	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		004	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		005	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		006	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		007	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		008	17D	-	-	-	-	-	-	-	-
		009	17D	-	-	-	-	-	-	-	-
		010	17D	-	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	SPHERO none	SIDERO none	TARGET none	TEAR none	B_STIP none	HJ none	AGGL none
1	0 µg/day	011	22R	-	-	-	-	-	-	-	-
		012	22R	-	-	-	-	-	-	-	-
		013	22R	-	-	-	-	-	-	-	-
		014	22R	-	-	-	-	-	-	-	-
		015	22R	-	-	-	-	-	-	-	-
2	30 µg/day	016	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		017	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		018	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		019	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		020	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		021	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	SPHERO none	SIDERO none	TARGET none	TEAR none	B_STIP none	HJ none	AGGL none
2	30 µg/day	022	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		023	17D	-	-	-	-	-	-	-	-
		024	17D	-	-	-	-	-	-	-	-
		025	17D	-	-	-	-	-	-	-	-
		026	22R	-	-	-	-	-	-	-	-
		027	22R	-	-	-	-	-	-	-	-
		028	22R	-	-	-	-	-	-	-	-
		029	22R	-	-	-	-	-	-	-	-
		030	22R	-	-	-	-	-	-	-	-
3	30 µg /day	031	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		032	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		033	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		034	4D	--	-	-	-	-	-	-	-

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Appendix 7

Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	SPHERO none	SIDERO none	TARGET none	TEAR none	B_STIP none	HJ none	AGGL none
3	30 µg /day	034	17D	-	-	-	-	-	-	-	-
		035	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		036	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		037	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		038	17D	-	-	-	-	-	-	-	-
		039	17D	-	-	-	-	-	-	-	-
		040	17D	-	-	-	-	-	-	-	-
		041	22R	-	-	-	-	-	-	-	-
		042	22R	-	-	-	-	-	-	-	-
		043	22R	-	-	-	-	-	-	-	-
		044	22R	-	-	-	-	-	-	-	-
		045	22R	-	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	CLPLT none	HGB_CRYS none	BASOPH none	ACANTH none	STOM none	OTHERM none	DOHLE none
1	0 µg/day	001	4D	--	-	-	-	-	-	-	-
			17D	-	Present	-	-	-	-	-	-
		002	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		003	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		004	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		005	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		006	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		007	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		008	17D	-	-	-	-	-	-	-	-
		009	17D	-	-	-	-	-	-	-	-
		010	17D	-	-	-	-	-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	CLPLT none	HGB_CRYS none	BASOPH none	ACANTH none	STOM none	OTHERM none	DOHLE none
1	0 µg/day	011	22R	-	-	-	-	-	-	-	-
		012	22R	-	-	-	-	-	-	-	-
		013	22R	-	-	-	-	-	-	-	-
		014	22R	-	-	-	-	-	-	-	-
		015	22R	-	-	-	-	-	-	-	-
2	30 µg/day	016	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		017	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		018	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		019	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		020	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		021	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-

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Hematology and Coagulation
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	CLPLT none	HGB_CRYS none	BASOPH none	ACANTH none	STOM none	OTHERM none	DOHLE none
2	30 µg/day	022	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		023	17D	-	-	-	-	-	-	-	-
		024	17D	-	-	-	-	-	-	-	-
		025	17D	-	-	-	-	-	-	-	-
		026	22R	-	-	-	-	-	-	-	-
		027	22R	-	-	-	-	-	-	-	-
		028	22R	-	-	-	-	-	-	-	-
		029	22R	-	-	-	-	-	-	-	-
		030	22R	-	-	-	-	-	-	-	-
3	30 µg /day	031	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		032	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		033	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		034	4D	--	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	CLPLT none	HGB_CRYS none	BASOPH none	ACANTH none	STOM none	OTHERM none	DOHLE none
3	30 µg /day	034	17D	-	-	-	-	-	-	-	-
		035	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		036	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		037	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		038	17D	-	-	-	-	-	-	-	-
		039	17D	-	-	-	-	-	-	-	-
		040	17D	-	-	-	-	-	-	-	-
		041	22R	-	-	-	-	-	-	-	-
		042	22R	-	-	-	-	-	-	-	-
		043	22R	-	-	-	-	-	-	-	-
		044	22R	-	-	-	-	-	-	-	-
		045	22R	-	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	HYSEG none	TOXIC_G none	TOXIC_V none	VACLYM none	PT_Rat sec		APTT sec		FIB mg/dL	
1	0 µg/day	001	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	-	CL	-	CL	-	CL
		002	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	14.0		14.8		273	
		003	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	-	QN	-	QN	-	QN
		004	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	14.8		14.9		249	
		005	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	14.4		14.7		239	
		006	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	14.6		13.3		275	
		007	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	14.9		10.5	RR	240	
		008	17D	-	-	-	-	-	14.2		15.1		259	
		009	17D	-	-	-	-	-	16.3		16.5		247	
		010	17D	-	-	-	-	-	13.9		15.5		243	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	HYSEG none	TOXIC_G none	TOXIC_V none	VACLYM none	PT_Rat sec		APTT sec		FIB mg/dL	
1	0 µg/day	011	22R	-	-	-	-	-	16.2		16.0		307	
		012	22R	-	-	-	-	-	15.8		17.0		250	
		013	22R	-	-	-	-	-	16.7		16.9		278	
		014	22R	-	-	-	-	-	14.4		15.9		225	
		015	22R	-	-	-	-	-	13.6		16.4		264	
2	30 µg/day	016	4D	--	-	-	-	-	-		-		-	
			17D	-	Present	-	-	-	15.4		16.8		618	RR
		017	4D	--	-	-	-	-	-		-		-	
			17D	-	Present	-	-	-	16.3		16.0		589	
		018	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	13.6		16.1		575	
		019	4D	--	-	-	-	-	-		-		-	
			17D	-	Present	-	-	-	-	QN	-	QN	-	QN
		020	4D	--	-	-	-	-	-		-		-	
			17D	-	Present	-	-	-	17.7		19.0		520	
		021	4D	--	-	-	-	-	-		-		-	
			17D	-	-	-	-	-	15.1		10.4	RR	611	RR

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	HYSEG none	TOXIC_G none	TOXIC_V none	VACLYM none	PT_Rat sec	APTT sec	FIB mg/dL	
2	30 µg/day	022	4D	--	-	-	-	-	-	-	-	
			17D	-	-	-	-	-	16.9	19.3	651	RR
		023	17D	-	-	-	-	-	15.1	15.8	626	RR
		024	17D	-	-	-	-	-	15.6	18.5	618	RR
		025	17D	-	-	-	-	-	15.0	16.6	562	
		026	22R	-	-	-	-	-	14.9	17.1	276	
		027	22R	-	-	-	-	-	18.5	18.4	264	
		028	22R	-	-	-	-	-	17.5	17.9	255	
		029	22R	-	-	-	-	-	17.0	18.6	240	
		030	22R	-	-	-	-	-	15.3	16.8	298	
3	30 µg /day	031	4D	--	-	-	-	-	-	-	-	
			17D	-	-	-	-	-	15.5	14.5	678	RR
		032	4D	--	-	-	-	-	-	-	-	
			17D	-	Present	-	-	-	15.3	12.8	611	RR
		033	4D	--	-	-	-	-	-	-	-	
			17D	-	-	-	-	-	16.3	18.2	589	
		034	4D	--	-	-	-	-	-	-	-	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	HYSEG none	TOXIC_G none	TOXIC_V none	VACLYM none	PT_Rat sec		APTT sec	FIB mg/dL	
3	30 µg /day	034	17D	-	Present	-	-	-	17.2		16.9	596	
		035	4D	--	-	-	-	-	-		-	-	
			17D	-	Present	-	-	-	16.2		18.1	678	RR
		036	4D	--	-	-	-	-	-		-	-	
			17D	-	-	-	-	-	16.5		18.2	582	
		037	4D	--	-	-	-	-	-		-	-	
			17D	-	-	-	-	-	17.5		18.0	618	RR
		038	17D	-	-	-	-	-	16.5		17.3	651	RR
		039	17D	-	-	-	-	-	16.8		17.0	549	
		040	17D	-	Present	-	-	-	15.7		16.8	509	
		041	22R	-	Present	-	-	-	18.5		18.2	266	
		042	22R	-	-	-	-	-	20.2	CE	17.9	258	
		043	22R	-	-	-	-	-	18.8		17.4	256	
		044	22R	-	-	-	-	-	20.1	CE	19.2	258	
		045	22R	-	-	-	-	-	15.8		17.9	282	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	RDW %
1	0 µg/day	046	4D	--	7.21	13.4	41.0	56.8	18.5	32.6	10.6
			17D	-	7.08	13.4	41.1	58.1	19.0	32.7	11.7
		047	4D	--	8.01	14.5	44.9	56.0	18.0	32.2	11.5
			17D	-	7.61	14.2	42.7	56.1	18.7	33.3	11.5
		048	4D	--	7.69	14.3	45.0	58.5	18.6	31.9	11.3
			17D	-	7.32	13.8	41.4	56.6	18.8	33.2	11.7
		049	4D	--	8.38	15.3	47.3	56.4	18.2	32.3	11.0
			17D	-	7.62	13.7	41.6	54.7	18.0	33.0	10.9
		050	4D	--	7.94	14.7	45.2	57.0	18.6	32.6	11.2
			17D	-	7.32	13.5	41.2	56.3	18.4	32.7	11.0
		051	4D	--	7.96	14.6	45.5	57.2	18.4	32.1	11.0
			17D	-	7.31	13.8	41.6	56.9	18.8	33.1	10.8
		052	4D	--	8.13	14.9	45.5	56.0	18.3	32.7	11.2
			17D	-	7.69	14.3	42.4	55.2	18.5	33.6	10.8
		053	17D	-	7.42	13.6	40.5	54.5	18.3	33.6	11.3
		054	17D	-	7.47	13.8	41.6	55.6	18.5	33.3	12.0
		055	17D	-	7.39	14.2	42.6	57.6	19.2	33.3	11.6

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL	HGB g/dL	HCT %	MCV fL		MCH pg	MCHC g/dL	RDW %	
1	0 µg/day	056	22R	-	7.39	12.9	39.2	53.1		17.4	32.9	11.2	
		057	22R	-	7.06	14.0	40.7	-	RW	19.8	34.3	-	RW
		058	22R	-	6.97	13.5	41.0	58.8		19.4	33.0	10.8	
		059	22R	-	7.25	13.2	39.3	54.2		18.2	33.6	10.8	
		060	22R	-	7.64	14.6	43.7	57.1		19.1	33.5	10.4	
2	30 µg/day	061	4D	--	7.59	14.4	44.4	58.5		19.0	32.5	10.9	
			17D	-	6.73	12.5	38.2	56.8		18.5	32.6	12.3	
		062	4D	--	7.09	13.6	41.0	57.8		19.2	33.2	11.3	
			17D	-	6.70	12.1	38.1	56.8		18.1	31.9	13.5	
		063	4D	--	7.22	12.7	41.1	56.9		17.6	31.0	12.1	
			17D	-	6.81	11.9	37.2	54.6		17.5	32.1	13.0	
		064	4D	--	7.49	14.0	42.9	57.3		18.7	32.6	11.3	
			17D	-	7.09	12.9	39.5	55.7		18.1	32.6	12.6	
		065	4D	--	7.30	12.8	38.7	53.1		17.6	33.1	11.6	
			17D	-	6.75	12.1	36.7	54.3		17.9	33.0	15.8	
		066	4D	--	7.39	13.8	41.9	56.6		18.7	33.0	11.0	
			17D	-	6.88	12.6	37.9	55.1		18.2	33.1	12.6	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL		HGB g/dL		HCT %		MCV fL		MCH pg		MCHC g/dL		RDW %	
2	30 µg/day	067	4D	--	7.59		13.6		42.5		55.9		17.9		32.0		11.5	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	17D	-	7.03		12.1		37.1		52.8		17.3		32.7		13.0	
		069	17D	-	6.65		12.5		38.9		58.5		18.8		32.2		13.5	
		070	17D	-	7.21		12.7		39.2		54.3		17.5		32.3		13.8	
		071	22R	-	7.72		13.8		42.2		54.6		17.9		32.8		13.4	
		072	22R	-	8.03		13.8		41.6		51.8		17.1		33.1		13.1	
		073	22R	-	7.73		14.0		43.0		55.7		18.1		32.5		13.0	
		074	22R	-	7.54		13.5		41.7		55.3		17.9		32.4		12.8	
		075	22R	-	8.17		14.5		43.8		53.7		17.8		33.1		12.9	
3	30 µg /day	076	4D	--	7.49		13.7		42.0		56.0		18.2		32.5		11.5	
			17D	-	6.65		11.7		35.7		53.7		17.6		32.7		13.1	
		077	4D	--	7.07		13.3		41.3		58.3		18.8		32.2		11.5	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		078	4D	--	7.67		14.4		42.8		56.2		18.8		33.6		13.4	
			17D	-	7.11		13.2		39.0		-	RW	18.5		33.8		-	RW
		079	4D	--	7.48		13.9		43.3		57.9		18.5		32.0		11.5	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RBC 10^6/uL		HGB g/dL		HCT %		MCV fL		MCH pg		MCHC g/dL		RDW %	
3	30 µg /day	079	17D	-	6.43		11.9		37.1		57.6		18.4		32.0		13.8	
		080	4D	--	7.70		13.2		41.8		54.3		17.2		31.7		12.2	
			17D	-	6.89		12.4		37.1		53.9		18.0		33.3		14.5	
		081	4D	--	7.43		12.6		39.3		52.9		17.0		32.1		11.9	
			17D	-	6.84		11.5		35.4		51.7		16.8		32.5		13.0	
		082	4D	--	7.45		13.8		42.2		56.6		18.6		32.8		11.8	
			17D	-	6.52		11.9		36.1		55.4		18.3		33.0		12.9	
		083	17D	-	7.41		13.1		40.1		54.1		17.6		32.6		13.0	
		084	17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		085	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		086	22R	-	7.57		14.0		43.0		56.8		18.5		32.6		12.9	
		087	22R	-	7.68		13.2		40.1		52.2		17.2		32.9		14.0	
		088	22R	-	7.86		14.4		43.3		55.1		18.4		33.3		13.1	
		089	22R	-	7.96		14.6		45.7		57.4		18.3		32.0		13.7	
		090	22R	-	7.45		14.5		42.8		57.4		19.5		34.0		12.9	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RETIC_P %	RETIC 10^3/uL	PLT 10^3/uL		MPV fL	WBC 10e3/uL	NEUT 10^3/uL	NEUT_P %
1	0 µg/day	046	4D	--	3.7	267	880		7.0	11.0	3.68	33.3
			17D	-	2.8	198	974		9.3	2.9	0.85	29.3
		047	4D	--	4.0	320	704		10.0	5.1	0.46	9.0
			17D	-	2.3	175	712		10.4	2.3	0.48	20.5
		048	4D	--	3.4	261	938		8.8	6.1	0.42	6.8
			17D	-	1.7	124	998		9.3	1.6	0.27	16.5
		049	4D	--	4.0	335	1014		8.3	5.2	0.62	12.0
			17D	-	2.2	168	980		8.9	2.9	0.51	17.5
		050	4D	--	4.6	365	1073		8.8	6.5	0.43	6.6
			17D	-	2.3	168	1050		9.2	2.2	0.55	24.3
		051	4D	--	3.4	271	953		9.2	4.2	0.37	8.8
			17D	-	2.1	154	882	SR	10.1	2.1	0.38	18.3
		052	4D	--	3.6	293	928		8.6	4.0	0.46	11.7
			17D	-	1.4	108	1019		9.2	2.0	0.28	14.2
		053	17D	-	2.4	178	929		10.0	1.7	0.36	21.5
		054	17D	-	2.5	187	701		9.5	2.1	0.23	11.3
		055	17D	-	3.1	229	824		9.1	1.8	0.18	10.1

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RETIC_P %	RETIC 10^3/uL	PLT 10^3/uL		MPV fL	WBC 10e3/uL		NEUT 10^3/uL	NEUT_P %	
1	0 µg/day	056	22R	-	2.6	192	843		9.0	1.7		0.25	14.6	
		057	22R	-	2.0	141	651		9.1	2.1		0.23	10.9	
		058	22R	-	2.7	188	803		9.2	2.4		0.33	14.0	
		059	22R	-	1.9	138	824		9.9	1.7		0.26	15.6	
		060	22R	-	1.4	107	817		8.8	3.8		0.19	4.9	SR
2	30 µg/day	061	4D	--	1.8	137	1130		8.7	8.5		2.66	31.2	
			17D	-	4.0	269	730		9.0	3.8		1.82	48.4	
		062	4D	--	1.6	113	966		8.9	8.0		2.43	30.5	
			17D	-	3.2	214	662	SR	9.5	6.2	SR	3.22	52.4	
		063	4D	--	2.3	166	910		9.1	5.2		1.24	23.9	
			17D	-	3.0	204	759		9.7	4.0		1.85	46.0	
		064	4D	--	2.5	187	1019		9.2	6.0		1.47	24.4	
			17D	-	2.9	206	699		9.5	4.9		1.74	35.4	
		065	4D	--	1.2	88	956		8.7	7.7		2.84	37.0	
			17D	-	2.8	189	871		9.3	5.6		3.12	56.2	
		066	4D	--	1.4	103	1042		9.2	11.4		3.02	26.5	
			17D	-	2.3	158	827		9.4	8.0		3.58	44.7	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RETIC_P %		RETIC 10^3/uL		PLT 10^3/uL		MPV fL		WBC 10e3/uL		NEUT 10^3/uL		NEUT_P %	
2	30 µg/day	067	4D	--	1.5		114		1004		8.6		8.1		2.48		30.5	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	17D	-	3.0		211		882		9.5		6.6		2.06		31.4	
		069	17D	-	5.2		346		881		9.5		6.5		2.81		43.0	
		070	17D	-	2.8		202		691		9.2		5.7		2.02		35.6	
		071	22R	-	2.2		170		738		9.5		2.5		0.33		13.3	
		072	22R	-	2.0		161		953		8.6		1.7		0.25		14.6	
		073	22R	-	1.7		131		797		9.1		3.2		0.96		29.8	
		074	22R	-	2.2		166		905		9.1		3.4		0.47		13.8	
		075	22R	-	1.8		147		798		8.8		2.3		0.40		17.7	
3	30 µg /day	076	4D	--	1.3		97		849		9.5		7.6		2.67		35.4	
			17D	-	3.0		200		714		9.8		6.1		3.08		50.6	
		077	4D	--	2.6		184		1066		9.0		8.0		3.30		41.4	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		078	4D	--	0.9		69		913		9.3		9.8		2.66		27.0	
			17D	-	2.5		178		682		10.2		9.0		4.07		45.0	
		079	4D	--	2.1		157		1160		8.9		7.9		2.58		32.7	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	RETIC_P %		RETIC 10^3/uL		PLT 10^3/uL		MPV fL		WBC 10e3/uL		NEUT 10^3/uL		NEUT_P %	
3	30 µg /day	079	17D	-	4.6		296		799		9.9		2.5		1.08		43.4	
		080	4D	--	1.7		131		1102	RP	7.5	RP	9.4		2.56		27.2	
			17D	-	2.4		165		944		9.9		6.1		2.78		45.3	
		081	4D	--	1.9		141		1044		8.6		7.9		2.59		32.8	
			17D	-	2.6		178		907		8.5		4.6		2.25		48.7	
		082	4D	--	2.1		156		681		10.1		9.4		3.79		40.3	
			17D	-	3.5		228		492		10.7		9.7		4.76		49.0	
		083	17D	-	2.4		178		765		9.1		6.6		2.13		32.0	
		084	17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		085	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		086	22R	-	1.7		129		729		9.0		1.4		0.30		21.7	
		087	22R	-	1.6		123		744		8.8		3.2		0.33		10.3	
		088	22R	-	1.3		102		872		9.2		1.7		0.21		12.5	
		089	22R	-	2.8		223		767		9.7		4.2		0.31		7.5	
		090	22R	-	1.4		104		798		9.2		3.1		0.24		7.8	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL	LYM_P %	MONO 10^3/uL	MONO_P %	EO 10^3/uL	EO_P %	BASO 10^3/uL
1	0 µg/day	046	4D	--	6.89	62.4	0.30	2.7	0.06	0.5	0.02
			17D	-	1.91	66.3	0.07	2.5	0.04	1.5	0.00
		047	4D	--	4.48	88.0	0.05	1.0	0.07	1.3	0.01
			17D	-	1.79	76.9	0.03	1.1	0.02	1.0	0.00
		048	4D	--	5.56	91.0	0.05	0.8	0.05	0.8	0.01
			17D	-	1.31	80.0	0.03	2.1	0.02	1.2	0.00
		049	4D	--	4.41	84.7	0.07	1.3	0.06	1.2	0.01
			17D	-	2.22	76.0	0.10	3.6	0.05	1.9	0.01
		050	4D	--	5.93	91.1	0.06	1.0	0.05	0.8	0.01
			17D	-	1.60	71.2	0.05	2.0	0.04	1.9	0.00
		051	4D	--	3.75	88.8	0.05	1.1	0.04	1.0	0.00
			17D	-	1.56	75.4	0.08	3.8	0.04	1.8	0.00
		052	4D	--	3.36	84.6	0.07	1.7	0.07	1.6	0.00
			17D	-	1.66	83.2	0.03	1.4	0.01	0.7	0.00
		053	17D	-	1.22	73.6	0.05	2.7	0.02	1.4	0.00
		054	17D	-	1.74	84.7	0.04	1.9	0.03	1.7	0.00
		055	17D	-	1.50	83.7	0.08	4.3	0.02	1.1	0.00

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL	LYM_P %	MONO 10^3/uL	MONO_P %	EO 10^3/uL	EO_P %	BASO 10^3/uL
1	0 µg/day	056	22R	-	1.40	81.2	0.03	1.7	0.03	1.8	0.00
		057	22R	-	1.77	85.3	0.04	2.0	0.02	1.1	0.00
		058	22R	-	1.97	82.5	0.04	1.8	0.03	1.1	0.00
		059	22R	-	1.38	81.5	0.01	0.8	0.03	1.6	0.00
		060	22R	-	3.56	92.8	0.02	0.6	0.05	1.2	0.00
2	30 µg/day	061	4D	--	5.47	64.1	0.16	1.9	0.10	1.2	0.02
			17D	-	1.72	45.7	0.12	3.2	0.05	1.4	0.00
		062	4D	--	4.92	61.6	0.19	2.4	0.11	1.4	0.02
			17D	-	2.30	37.4	0.19	3.0	0.19	3.1	0.01
		063	4D	--	3.74	71.7	0.10	2.0	0.07	1.3	0.01
			17D	-	1.92	47.6	0.11	2.6	0.11	2.7	0.01
		064	4D	--	4.25	70.8	0.14	2.3	0.06	1.0	0.00
			17D	-	2.86	58.2	0.15	3.0	0.07	1.5	0.01
		065	4D	--	4.33	56.5	0.27	3.5	0.10	1.3	0.02
			17D	-	2.14	38.6	0.13	2.4	0.08	1.5	0.00
		066	4D	--	7.90	69.2	0.21	1.9	0.11	1.0	0.03
			17D	-	4.00	50.0	0.20	2.5	0.11	1.3	0.01

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL		LYM_P %		MONO 10^3/uL		MONO_P %		EO 10^3/uL		EO_P %		BASO 10^3/uL	
2	30 µg/day	067	4D	--	5.34		65.8		0.16		1.9		0.06		0.8		0.02	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	17D	-	4.04		61.5		0.19		3.0		0.10		1.4		0.01	
		069	17D	-	3.43		52.6		0.16		2.5		0.05		0.7		0.01	
		070	17D	-	3.09		54.4		0.14		2.5		0.07		1.3		0.01	
		071	22R	-	2.07		83.4		0.04		1.6		0.03		1.3		0.00	
		072	22R	-	1.39		81.0		0.04		2.3		0.03		1.7		0.00	
		073	22R	-	2.16		67.1		0.06		2.0		0.01		0.4		0.00	
		074	22R	-	2.88		83.5		0.04		1.1		0.03		0.8		0.00	
		075	22R	-	1.75		77.5		0.06		2.6		0.04		1.6		0.00	
3	30 µg /day	076	4D	--	4.38		57.9		0.25		3.3		0.12		1.6		0.02	
			17D	-	2.61		43.0		0.12		2.0		0.10		1.7		0.01	
		077	4D	--	4.31		54.1		0.15		1.9		0.12		1.5		0.02	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		078	4D	--	6.60		67.1		0.20		2.1		0.20		2.1		0.03	
			17D	-	4.29		47.5		0.18		2.0		0.11		1.3		0.01	
		079	4D	--	4.89		62.0		0.18		2.3		0.10		1.3		0.02	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LYM 10^3/uL		LYM_P %		MONO 10^3/uL		MONO_P %		EO 10^3/uL		EO_P %		BASO 10^3/uL	
3	30 µg /day	079	17D	-	1.14		45.8		0.09		3.7		0.03		1.4		0.00	
		080	4D	--	6.35		67.6		0.25		2.7		0.09		1.0		0.03	
			17D	-	2.91		47.5		0.21		3.4		0.14		2.3		0.01	
		081	4D	--	4.61		58.3		0.33		4.2		0.09		1.1		0.03	
			17D	-	2.03		43.9		0.12		2.6		0.08		1.7		0.01	
		082	4D	--	5.04		53.7		0.28		3.0		0.14		1.5		0.02	
			17D	-	4.29		44.2		0.26		2.7		0.15		1.5		0.02	
		083	17D	-	3.94		59.3		0.25		3.7		0.07		1.1		0.01	
		084	17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		085	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		086	22R	-	1.03		73.8		0.03		2.3		0.02		1.8		0.00	
		087	22R	-	2.79		86.4		0.06		1.8		0.02		0.7		0.00	
		088	22R	-	1.42		82.5		0.05		2.8		0.03		1.5		0.00	
		089	22R	-	3.63		87.2		0.10		2.5		0.07		1.6		0.01	
		090	22R	-	2.71		87.8		0.06		2.1		0.04		1.4		0.00	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	BASO_P %	LUC 10^3/uL	LUC_P %	MORPH none	POIK none	BURR none	SCHISTO none
1	0 µg/day	046	4D	--	0.2	0.09	0.8	-	-	-	-
			17D	-	0.0	0.01	0.5	Normal	-	-	-
		047	4D	--	0.2	0.02	0.4	-	-	-	-
			17D	-	0.1	0.01	0.4	Normal	-	-	-
		048	4D	--	0.2	0.03	0.5	-	-	-	-
			17D	-	0.0	0.00	0.2	Normal	-	-	-
		049	4D	--	0.1	0.03	0.6	-	-	-	-
			17D	-	0.2	0.02	0.8	Normal	-	-	-
		050	4D	--	0.1	0.02	0.4	-	-	-	-
			17D	-	0.0	0.01	0.4	-	-	-	-
		051	4D	--	0.1	0.01	0.3	-	-	-	-
			17D	-	0.0	0.01	0.7	Normal	-	-	-
		052	4D	--	0.1	0.01	0.4	-	-	-	-
			17D	-	0.0	0.01	0.3	-	-	-	-
		053	17D	-	0.1	0.01	0.6	-	-	-	-
		054	17D	-	0.0	0.01	0.4	-	-	-	-
		055	17D	-	0.1	0.01	0.7	-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	BASO_P %	LUC 10^3/uL	LUC_P %	MORPH none	POIK none	BURR none	SCHISTO none
1	0 µg/day	056	22R	-	0.2	0.01	0.5	Normal	-	-	-
		057	22R	-	0.1	0.01	0.6	Normal	-	-	-
		058	22R	-	0.0	0.02	0.7	Normal	-	-	-
		059	22R	-	0.0	0.01	0.6	Normal	-	-	-
		060	22R	-	0.1	0.02	0.5	Reported	-	Present	-
2	30 µg/day	061	4D	--	0.2	0.13	1.5	-	-	-	-
			17D	-	0.0	0.05	1.3	Reported	-	-	-
		062	4D	--	0.2	0.32	4.0	-	-	-	-
			17D	-	0.2	0.24	3.9	Reported	-	-	-
		063	4D	--	0.2	0.05	1.0	-	-	-	-
			17D	-	0.1	0.04	0.9	Reported	-	-	-
		064	4D	--	0.1	0.08	1.3	-	-	-	-
			17D	-	0.1	0.09	1.8	Reported	-	Present	-
		065	4D	--	0.3	0.11	1.4	-	-	-	-
			17D	-	0.1	0.07	1.2	-	-	-	-
		066	4D	--	0.2	0.14	1.2	-	-	-	-
			17D	-	0.1	0.12	1.5	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	BASO_P %		LUC 10^3/uL		LUC_P %		MORPH none		POIK none		BURR none		SCHISTO none	
2	30 µg/day	067	4D	--	0.2		0.05		0.7		-		-		-		-	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	17D	-	0.2		0.17		2.5		-		-		-		-	
		069	17D	-	0.1		0.07		1.1		-		-		-		-	
		070	17D	-	0.2		0.34		6.0	SR	Reported		-		-		-	
		071	22R	-	0.1		0.00		0.1		Normal		-		-		-	
		072	22R	-	0.0		0.01		0.5		Normal		-		-		-	
		073	22R	-	0.0		0.02		0.7		Normal		-		-		-	
		074	22R	-	0.1		0.02		0.6		Reported		-		Present		-	
		075	22R	-	0.2		0.01		0.5		Reported		-		Present		-	
3	30 µg /day	076	4D	--	0.3		0.12		1.6		-		-		-		-	
			17D	-	0.2		0.15		2.4		Reported		-		-		-	
		077	4D	--	0.3		0.07		0.9		-		-		-		-	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		078	4D	--	0.3		0.14		1.4		-		-		-		-	
			17D	-	0.2		0.37		4.1		Reported		-		-		-	
		079	4D	--	0.2		0.11		1.4		-		-		-		-	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	BASO_P %		LUC 10^3/uL		LUC_P %		MORPH none		POIK none		BURR none		SCHISTO none	
3	30 µg /day	079	17D	-	0.2		0.14		5.6	SR	Reported		-		-		-	
		080	4D	--	0.3		0.11		1.2		-		-		-		-	
			17D	-	0.2		0.08		1.3		Reported		-		Present		-	
		081	4D	--	0.3		0.26		3.3		-		-		-		-	
			17D	-	0.2		0.13		2.8		-		-		-		-	
		082	4D	--	0.2		0.12		1.3		-		-		-		-	
			17D	-	0.2		0.22		2.3		Reported		-		Present		-	
		083	17D	-	0.2		0.24		3.7		-		-		-		-	
		084	17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		085	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		086	22R	-	0.1		0.00		0.3		Normal		-		-		-	
		087	22R	-	0.0		0.03		0.9		Normal		-		-		-	
		088	22R	-	0.3		0.01		0.4		Normal		-		-		-	
		089	22R	-	0.2		0.04		0.9		Reported		-		Present		-	
		090	22R	-	0.1		0.03		0.9		Reported		-		Present		-	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	SPHERO none	SIDERO none	TARGET none	TEAR none	B_STIP none	HJ none	AGGL none
1	0 µg/day	046	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		047	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		048	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		049	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		050	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		051	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		052	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		053	17D	-	-	-	-	-	-	-	-
		054	17D	-	-	-	-	-	-	-	-
		055	17D	-	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	SPHERO none	SIDERO none	TARGET none	TEAR none	B_STIP none	HJ none	AGGL none
1	0 µg/day	056	22R	-	-	-	-	-	-	-	-
		057	22R	-	-	-	-	-	-	-	-
		058	22R	-	-	-	-	-	-	-	-
		059	22R	-	-	-	-	-	-	-	-
		060	22R	-	-	-	-	-	-	-	-
2	30 µg/day	061	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		062	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		063	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		064	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		065	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		066	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	SPHERO none		SIDERO none		TARGET none		TEAR none		B_STIP none		HJ none		AGGL none	
2	30 µg/day	067	4D	--	-		-		-		-		-		-		-	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	17D	-	-		-		-		-		-		-		-	
		069	17D	-	-		-		-		-		-		-		-	
		070	17D	-	-		-		-		-		-		-		-	
		071	22R	-	-		-		-		-		-		-		-	
		072	22R	-	-		-		-		-		-		-		-	
		073	22R	-	-		-		-		-		-		-		-	
		074	22R	-	-		-		-		-		-		-		-	
		075	22R	-	-		-		-		-		-		-		-	
3	30 µg /day	076	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		077	4D	--	-		-		-		-		-		-		-	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		078	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		079	4D	--	-		-		-		-		-		-		-	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	SPHERO none		SIDERO none		TARGET none		TEAR none		B_STIP none		HJ none		AGGL none	
3	30 µg /day	079	17D	-	-		-		-		-		-		-		-	
		080	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		081	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		082	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		083	17D	-	-		-		-		-		-		-		-	
		084	17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		085	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		086	22R	-	-		-		-		-		-		-		-	
		087	22R	-	-		-		-		-		-		-		-	
		088	22R	-	-		-		-		-		-		-		-	
		089	22R	-	-		-		-		-		-		-		-	
		090	22R	-	-		-		-		-		-		-		-	

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	CLPLT none	HGB_CRYS none	BASOPH none	ACANTH none	STOM none	OTHERM none	DOHLE none
1	0 µg/day	046	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		047	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		048	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		049	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		050	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		051	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		052	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		053	17D	-	-	-	-	-	-	-	-
		054	17D	-	-	-	-	-	-	-	-
		055	17D	-	-	-	-	-	-	-	-

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Hematology and Coagulation

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	CLPLT none	HGB_CRYS none	BASOPH none	ACANTH none	STOM none	OTHERM none	DOHLE none
1	0 µg/day	056	22R	-	-	-	-	-	-	-	-
		057	22R	-	-	-	-	-	-	-	-
		058	22R	-	-	-	-	-	-	-	-
		059	22R	-	-	-	-	-	-	-	-
		060	22R	-	-	-	-	-	-	-	-
2	30 µg/day	061	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		062	4D	--	-	-	-	-	-	-	-
			17D	-	Present	-	-	-	-	-	-
		063	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		064	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		065	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-
		066	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	-	-	-

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	CLPLT none		HGB_CRYS none		BASOPH none		ACANTH none		STOM none		OTHERM none		DOHLE none	
2	30 µg/day	067	4D	--	-		-		-		-		-		-		-	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	17D	-	-		-		-		-		-		-		-	
		069	17D	-	-		-		-		-		-		-		-	
		070	17D	-	-		-		-		-		-		-		-	
		071	22R	-	-		-		-		-		-		-		-	
		072	22R	-	-		-		-		-		-		-		-	
		073	22R	-	-		-		-		-		-		-		-	
		074	22R	-	-		-		-		-		-		-		-	
		075	22R	-	-		-		-		-		-		-		-	
3	30 µg /day	076	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		077	4D	--	-		-		-		-		-		-		-	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		078	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		079	4D	--	-		-		-		-		-		-		-	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	CLPLT none		HGB_CRYS none		BASOPH none		ACANTH none		STOM none		OTHERM none		DOHLE none	
3	30 µg /day	079	17D	-	-		-		-		-		-		-		-	
		080	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		081	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		082	4D	--	-		-		-		-		-		-		-	
			17D	-	-		-		-		-		-		-		-	
		083	17D	-	-		-		-		-		-		-		-	
		084	17D	-	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL	-	CL
		085	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		086	22R	-	-		-		-		-		-		-		-	
		087	22R	-	-		-		-		-		-		-		-	
		088	22R	-	-		-		-		-		-		-		-	
		089	22R	-	-		-		-		-		-		-		-	
		090	22R	-	-		-		-		-		-		-		-	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	HYSEG none	TOXIC_G none	TOXIC_V none	VACLYM none	PT_Rat sec	APTT sec	FIB mg/dL
1	0 µg/day	046	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	14.4	15.6	215
		047	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	15.1	16.4	219
		048	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	14.7	16.3	201
		049	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	13.5	15.9	235
		050	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	13.4	14.2	263
		051	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	13.5	15.0	204
		052	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	14.6	16.0	220
		053	17D	-	-	-	-	-	14.6	15.9	188
		054	17D	-	-	-	-	-	14.9	14.9	183
		055	17D	-	-	-	-	-	12.5	14.3	244

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	HYSEG none	TOXIC_G none	TOXIC_V none	VACLYM none	PT_Rat sec	APTT sec	FIB mg/dL
1	0 µg/day	056	22R	-	-	-	-	-	14.3	16.2	189
		057	22R	-	-	-	-	-	12.0	15.7	185
		058	22R	-	-	-	-	-	13.3	17.3	173
		059	22R	-	-	-	-	-	13.0	17.8	171
		060	22R	-	-	-	-	-	12.9	17.1	214
2	30 µg/day	061	4D	--	-	-	-	-	-	-	-
			17D	-	Present	-	-	-	15.2	12.7	520
		062	4D	--	-	-	-	-	-	-	-
			17D	-	Present	-	-	-	13.7	15.2	549
		063	4D	--	-	-	-	-	-	-	-
			17D	-	Present	-	-	-	14.2	16.1	462
		064	4D	--	-	-	-	-	-	-	-
			17D	-	Present	-	-	-	17.0	14.3	509
		065	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	14.8	15.7	526
		066	4D	--	-	-	-	-	-	-	-
			17D	-	-	-	-	-	14.6	17.0	526

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Female

Group Number	Dose	Animal	Day	HPD	HYSEG none		TOXIC_G none		TOXIC_V none		VACLYM none		PT_Rat sec		APTT sec		FIB mg/dL	
2	30 µg/day	067	4D	--	-		-		-		-		-		-		-	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	QN	-	QN	-	QN
		068	17D	-	-		-		-		-		14.5		15.7		504	
		069	17D	-	-		-		-		-		15.9		16.0		603	RR
		070	17D	-	Present		-		-		-		14.1		17.3		678	RR
		071	22R	-	-		-		-		-		13.8		17.0		165	
		072	22R	-	-		-		-		-		13.5		16.7		209	
		073	22R	-	-		-		-		-		13.9		16.4		210	
		074	22R	-	-		-		-		-		14.7		17.5		197	
		075	22R	-	-		-		-		-		12.4		18.7		202	
3	30 µg /day	076	4D	--	-		-		-		-		-		-		-	
			17D	-	Present		-		-		-		14.9		16.7		643	RR
		077	4D	--	-		-		-		-		-		-		-	
			17D	-	-	CL	-	CL	-	CL	-	CL	-	QN	-	QN	-	QN
		078	4D	--	-		-		-		-		-		-		-	
			17D	-	Present		-		-		-		15.6		16.6		603	RR
		079	4D	--	-		-		-		-		-		-		-	

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Appendix 7

Hematology and Coagulation
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	HYSEG none		TOXIC_G none		TOXIC_V none		VACLYM none		PT_Rat sec	APTT sec		FIB mg/dL	
3	30 µg /day	079	17D	-	Present		-		-		-		16.3	16.6		634	RR
		080	4D	--	-		-		-		-		-	-		-	
			17D	-	Present		-		-		-		14.3	16.2		531	
		081	4D	--	-		-		-		-		-	-		-	
			17D	-	-		-		-		-		15.2	15.2		520	
		082	4D	--	-		-		-		-		-	-		-	
			17D	-	Present		-		-		-		15.6	15.9		499	
		083	17D	-	-		-		-		-		15.3	16.9		603	RR
		084	17D	-	-	CL	-	CL	-	CL	-	CL	17.1	8.8	RR	515	
		085	17D	-	-	QN	-	QN	-	QN	-	QN	14.1	10.1	RR	520	
		086	22R	-	-		-		-		-		12.9	16.2		188	
		087	22R	-	-		-		-		-		14.0	17.2		160	
		088	22R	-	-		-		-		-		14.0	17.7		182	
		089	22R	-	-		-		-		-		14.1	16.2		189	
		090	22R	-	-		-		-		-		12.9	17.5		206	

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Appendix 8

Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
ALP	Alkaline Phosphatase
GGT	Gamma Glutamyl Transferase
TBIL	Bilirubin, Total
CHOL	Cholesterol
TRIG	Triglycerides
GLUC	Glucose
TP	Protein, Total
ALB	Albumin
GLOB	Globulin
AG	Albumin/Globulin Ratio
BUN	Blood Urea Nitrogen
CREA	Creatinine
PHOS	Phosphorus
CA	Calcium
NA	Sodium
K	Potassium
CL	Chloride
HEM_IND	Hemolytic Index

Parameter	Description
ICT_IND	Icterus Index
LIP_IND	Lipemic Index
A2M	Alpha-2-Macroglobulin
A1AGP	Alpha-1 Acid Glycoprotein

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Comment	Description
NS	No Sample
QN	Quantity Not Sufficient
RR	Result repeated

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Clinical Chemistry
20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

- Value not applicable;

Note: Each interval/day will be concatenated with the phase name abbreviation

HPD = Hours Post Dose; U = Unscheduled

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
1	0 µg/day	001	17D	-	22	63	92	<3	<0.1	46	69
		002	17D	-	18	72	88	<3	<0.1	50	87
		003	17D	-	17	71	79	<3	0.1	62	42
		004	17D	-	20	71	85	<3	<0.1	54	64
		005	17D	-	19	70	145	<3	<0.1	54	64
		006	17D	-	17	76	86	<3	<0.1	44	56
		007	17D	-	20	75	146	<3	<0.1	46	73
		008	4D	---	34	88	130	<3	<0.1	57	35
			17D	-	15	75	74	<3	<0.1	44	30
		009	4D	---	27	99	135	<3	<0.1	60	76
			17D	-	19	80	88	<3	<0.1	57	45
		010	4D	---	32	108	179	<3	<0.1	78	103
			17D	-	14	64	93	<3	<0.1	60	58
		011	4D	---	28	84	173	<3	<0.1	54	59
			22R	-	25	108	85	<3	<0.1	49	42
		012	4D	---	16	96	171	<3	<0.1	61	33
			22R	-	17	89	93	<3	<0.1	56	80

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
1	0 µg/day	013	4D	---	27	102	131	<3	<0.1	52	44
			22R	-	18	95	74	<3	<0.1	44	35
		014	4D	---	40	86	134	<3	<0.1	72	91
			22R	-	18	82	63	<3	<0.1	52	37
		015	4D	---	29	93	280	<3	<0.1	70	55
			22R	-	18	85	107	<3	<0.1	63	51
2	30 µg/day	016	17D	-	20	92	93	<3	0.1	37	44
		017	17D	-	25	94	126	<3	<0.1	33	38
		018	17D	-	24	84	94	<3	0.1	42	44
		019	17D	-	20	63	105	<3	<0.1	44	38
		020	17D	-	24	105	91	<3	<0.1	40	31
		021	17D	-	16	68	114	<3	<0.1	41	22
		022	17D	-	18	63	67	<3	<0.1	28	28
		023	4D	---	36	104	199	<3	<0.1	47	42
			17D	-	25	103	132	<3	<0.1	48	30
		024	4D	---	47	122	193	<3	<0.1	53	32
			17D	-	33	89	100	<3	<0.1	43	28

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
2	30 µg/day	025	4D	---	32	91	214	<3	<0.1	66	44
			17D	-	24	81	112	<3	<0.1	46	33
		026	4D	---	33	126	182	<3	<0.1	58	52
			22R	-	17	103	81	<3	<0.1	68	77
		027	4D	---	29	108	201	<3	<0.1	43	31
			22R	-	22	105	75	<3	<0.1	56	46
		028	4D	---	25	97	136	<3	<0.1	55	34
			22R	-	16	102	71	<3	<0.1	66	40
		029	4D	---	34	87	206	<3	<0.1	49	60
			22R	-	17	86	76	<3	<0.1	59	42
		030	4D	---	30	90	232	<3	<0.1	49	47
			22R	-	16	74	95	<3	<0.1	56	49
3	30 µg /day	031	17D	-	18	76	97	<3	<0.1	32	29
		032	17D	-	22	72	103	<3	<0.1	30	38
		033	17D	-	21	88	101	<3	<0.1	35	59
		034	17D	-	19	91	95	<3	<0.1	44	28
		035	17D	-	24	94	152	<3	0.1	46	38

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
3	30 µg /day	036	17D	-	19	81	80	<3	<0.1	28	28
		037	17D	-	26	88	113	<3	<0.1	32	31
		038	4D	---	24	94	206	<3	<0.1	39	27
			17D	-	20	94	146	<3	<0.1	38	24
		039	4D	---	32	110	202	<3	<0.1	78	70
			17D	-	16	99	97	<3	<0.1	55	44
		040	4D	---	29	81	216	<3	<0.1	46	61
			17D	-	23	85	116	<3	<0.1	32	40
		041	4D	---	41	82	186	<3	<0.1	58	62
			22R	-	22	93	94	<3	<0.1	54	71
		042	4D	---	27	93	177	<3	<0.1	45	71
			22R	-	16	95	68	<3	<0.1	54	48
		043	4D	---	26	123	143	<3	<0.1	41	26
			22R	-	14	105	66	<3	<0.1	54	38
		044	4D	---	24	97	153	<3	<0.1	37	33
			22R	-	18	96	79	<3	<0.1	55	28
		045	4D	---	27	102	223	<3	<0.1	70	65

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
3	30 µg /day	045	22R	-	17	96	110	<3	<0.1	64	43

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL	TP g/dL	ALB g/dL	GLOB g/dL	AG none	BUN mg/dL	CREA mg/dL
1	0 µg/day	001	17D	-	148	5.7	3.7	2.0	1.8	22	0.3
		002	17D	-	138	5.3	3.4	1.9	1.8	22	0.3
		003	17D	-	136	5.2	3.4	1.8	1.9	18	0.3
		004	17D	-	100	5.2	3.4	1.8	1.9	12	0.2
		005	17D	-	137	5.8	3.8	2.0	1.9	24	0.2
		006	17D	-	138	5.4	3.5	1.9	1.8	16	0.3
		007	17D	-	104	5.8	3.7	2.1	1.8	15	0.2
		008	4D	---	98	5.9	3.8	2.1	1.8	26	0.3
			17D	-	152	5.0	3.3	1.7	1.9	23	0.3
		009	4D	---	100	5.9	3.9	2.0	2.0	20	0.3
			17D	-	128	5.5	3.6	1.9	1.9	18	0.2
		010	4D	---	129	6.2	4.0	2.2	1.8	28	0.3
			17D	-	136	5.0	3.2	1.8	1.8	18	0.2
		011	4D	---	109	5.8	3.8	2.0	1.9	19	0.3
			22R	-	110	5.9	3.8	2.1	1.8	20	0.3
		012	4D	---	124	6.4	4.2	2.2	1.9	29	0.4
			22R	-	157	5.6	3.6	2.0	1.8	16	0.3

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL	TP g/dL	ALB g/dL	GLOB g/dL	AG none	BUN mg/dL	CREA mg/dL
1	0 µg/day	013	4D	---	90	6.1	4.0	2.1	1.9	18	0.3
			22R	-	117	5.9	3.8	2.1	1.8	17	0.3
		014	4D	---	117	6.3	4.1	2.2	1.9	20	0.3
			22R	-	121	6.0	3.8	2.2	1.7	16	0.2
		015	4D	---	123	6.2	4.0	2.2	1.8	30	0.3
			22R	-	180	5.7	3.6	2.1	1.7	16	0.3
2	30 µg/day	016	17D	-	143	5.9	3.6	2.3	1.6	23	0.4
		017	17D	-	100	5.8	3.6	2.2	1.6	16	0.2
		018	17D	-	142	5.3	3.4	1.9	1.8	24	0.3
		019	17D	-	129	5.9	3.7	2.2	1.7	16	0.3
		020	17D	-	102	5.0	3.1	1.9	1.6	14	0.2
		021	17D	-	114	5.7	3.4	2.3	1.5	19	0.2
		022	17D	-	125	5.1	3.2	1.9	1.7	20	0.2
		023	4D	---	100	5.6	3.6	2.0	1.8	27	0.3
			17D	-	103	5.9	3.7	2.2	1.7	18	0.3
		024	4D	---	79	6.1	3.9	2.2	1.8	24	0.3
			17D	-	118	5.2	3.3	1.9	1.7	16	0.2

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL	TP g/dL	ALB g/dL	GLOB g/dL	AG none	BUN mg/dL	CREA mg/dL
2	30 µg/day	025	4D	---	89	6.0	3.8	2.2	1.7	22	0.3
			17D	-	98	5.3	3.3	2.0	1.6	20	0.2
		026	4D	---	97	5.8	3.6	2.2	1.6	25	0.2
			22R	-	149	6.2	3.9	2.3	1.7	18	0.3
		027	4D	---	116	5.9	3.7	2.2	1.7	35	0.3
			22R	-	138	6.1	3.8	2.3	1.7	17	0.3
		028	4D	---	115	5.6	3.5	2.1	1.7	25	0.3
			22R	-	98	5.9	3.7	2.2	1.7	16	0.3
		029	4D	---	98	6.2	3.9	2.3	1.7	23	0.3
			22R	-	96	6.1	3.9	2.2	1.8	19	0.2
		030	4D	---	91	6.0	3.7	2.3	1.6	27	0.3
			22R	-	126	6.1	3.8	2.3	1.7	16	0.3
3	30 µg /day	031	17D	-	124	5.1	3.1	2.0	1.6	25	0.3
		032	17D	-	119	5.2	3.3	1.9	1.7	19	0.3
		033	17D	-	160	6.0	3.8	2.2	1.7	22	0.3
		034	17D	-	139	5.3	3.3	2.0	1.6	22	0.3
		035	17D	-	100	6.0	3.7	2.3	1.6	21	0.3

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL	TP g/dL	ALB g/dL	GLOB g/dL	AG none	BUN mg/dL	CREA mg/dL
3	30 µg /day	036	17D	-	158	5.2	3.3	1.9	1.7	17	0.2
		037	17D	-	120	5.6	3.5	2.1	1.7	18	0.3
		038	4D	---	78	5.9	3.8	2.1	1.8	22	0.2
			17D	-	98	5.3	3.3	2.0	1.6	21	0.3
		039	4D	---	91	6.1	3.8	2.3	1.7	25	0.2
			17D	-	118	5.3	3.3	2.0	1.6	18	0.2
		040	4D	---	110	5.7	3.6	2.1	1.7	22	0.3
			17D	-	90	5.1	3.2	1.9	1.7	16	0.2
		041	4D	---	101	5.9	3.7	2.2	1.7	20	0.3
			22R	-	142	6.0	3.8	2.2	1.7	20	0.3
		042	4D	---	131	6.0	3.8	2.2	1.7	25	0.3
			22R	-	124	5.8	3.7	2.1	1.8	12	0.3
		043	4D	---	85	5.4	3.4	2.0	1.7	23	0.2
			22R	-	117	5.7	3.5	2.2	1.6	17	0.2
		044	4D	---	109	5.8	3.6	2.2	1.6	29	0.3
			22R	-	119	6.0	3.8	2.2	1.7	13	0.3
		045	4D	---	95	6.0	3.7	2.3	1.6	24	0.3

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL	TP g/dL	ALB g/dL	GLOB g/dL	AG none	BUN mg/dL	CREA mg/dL
3	30 µg /day	045	22R	-	97	6.0	3.8	2.2	1.7	20	0.3

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL		CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
1	0 µg/day	001	17D	-	8.8		9.8	146	4.2	106	Negative	Negative
		002	17D	-	8.3		9.7	145	4.2	105	Slight	Negative
		003	17D	-	8.6		10.0	143	4.6	105	Negative	Negative
		004	17D	-	7.7		9.7	142	4.2	104	Negative	Negative
		005	17D	-	10.2		10.2	143	4.5	103	Negative	Negative
		006	17D	-	8.3		9.9	143	4.3	105	Negative	Negative
		007	17D	-	8.9		10.4	145	4.3	105	Negative	Negative
		008	4D	---	7.1		9.5	144	4.2	102	Negative	Negative
			17D	-	9.7		9.9	144	4.2	105	Slight	Negative
		009	4D	---	7.3		9.4	143	4.1	101	Negative	Negative
			17D	-	8.7		9.9	145	4.1	104	Negative	Negative
		010	4D	---	7.6		9.7	144	5.0	100	Negative	Negative
			17D	-	8.0		9.1	144	4.4	106	Negative	Negative
		011	4D	---	7.3		10.0	144	4.7	102	Slight	Negative
			22R	-	4.7	RR	9.4	142	4.2	106	Negative	Negative
		012	4D	---	6.8		9.9	148	4.6	109	Slight	Negative
			22R	-	6.2		9.3	142	4.4	106	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
1	0 µg/day	013	4D	---	6.6	9.6	144	4.3	102	Slight	Negative
			22R	-	7.2	9.5	143	4.0	106	Slight	Negative
		014	4D	---	7.6	10.1	145	4.2	102	Negative	Negative
			22R	-	7.2	9.6	143	4.3	107	Slight	Negative
		015	4D	---	8.4	9.9	143	4.5	101	Slight	Negative
			22R	-	7.5	9.4	142	3.7	103	Negative	Negative
2	30 µg/day	016	17D	-	7.2	9.8	141	4.4	102	Negative	Negative
		017	17D	-	8.0	10.1	142	4.4	101	Negative	Negative
		018	17D	-	7.6	9.3	138	4.1	101	Negative	Negative
		019	17D	-	7.5	10.2	144	4.4	105	Negative	Negative
		020	17D	-	8.2	9.2	141	4.4	104	Negative	Negative
		021	17D	-	8.2	9.9	142	4.5	102	Slight	Negative
		022	17D	-	8.6	9.7	143	5.0	106	Negative	Negative
		023	4D	---	7.1	9.3	145	4.4	104	Negative	Negative
			17D	-	8.2	10.2	144	4.4	105	Negative	Negative
		024	4D	---	7.7	9.8	145	4.5	102	Negative	Negative
			17D	-	9.2	9.8	144	4.2	105	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
2	30 µg/day	025	4D	---	7.1	9.9	144	4.3	102	Negative	Negative
			17D	-	8.4	10.0	144	3.8	103	Negative	Negative
		026	4D	---	7.9	9.7	143	4.8	101	Negative	Negative
			22R	-	6.4	9.9	142	4.4	105	Negative	Negative
		027	4D	---	7.3	9.4	142	4.5	101	Negative	Negative
			22R	-	6.9	9.4	142	4.6	107	Slight	Negative
		028	4D	---	6.7	9.3	143	4.5	102	Negative	Negative
			22R	-	7.6	9.2	143	4.0	107	Negative	Negative
		029	4D	---	7.5	9.8	146	4.6	102	Negative	Negative
			22R	-	6.8	9.2	144	4.3	105	Negative	Negative
		030	4D	---	8.0	10.0	145	4.8	102	Negative	Negative
			22R	-	6.6	9.5	142	4.0	106	Negative	Negative
3	30 µg /day	031	17D	-	7.6	9.2	140	4.2	105	Slight	Negative
		032	17D	-	6.5	9.4	143	4.1	106	Negative	Negative
		033	17D	-	6.7	10.0	143	4.6	103	Negative	Negative
		034	17D	-	8.5	9.3	139	4.2	102	Negative	Negative
		035	17D	-	7.9	10.0	143	4.3	104	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
3	30 µg /day	036	17D	-	8.4	9.6	143	4.2	104	Negative	Negative
		037	17D	-	9.6	9.7	142	4.7	103	Slight	Negative
		038	4D	---	7.5	9.4	143	4.5	102	Negative	Negative
			17D	-	8.2	9.4	145	4.3	106	Slight	Negative
		039	4D	---	7.8	10.1	145	4.6	99	Negative	Negative
			17D	-	8.7	9.9	144	4.2	104	Negative	Negative
		040	4D	---	7.1	9.7	145	4.2	101	Negative	Negative
			17D	-	8.0	9.4	145	4.4	105	Negative	Negative
		041	4D	---	8.1	10.0	143	4.7	100	Negative	Negative
			22R	-	6.8	9.3	144	4.1	106	Negative	Negative
		042	4D	---	7.0	9.7	144	5.0	101	Negative	Negative
			22R	-	5.6	9.2	144	3.9	108	Negative	Negative
		043	4D	---	7.5	9.5	142	4.7	103	Negative	Negative
			22R	-	7.0	9.5	143	4.4	107	Slight	Negative
		044	4D	---	7.9	9.4	143	4.5	102	Negative	Negative
			22R	-	7.4	9.5	142	4.3	105	Negative	Negative
		045	4D	---	7.7	10.2	145	5.1	102	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
3	30 µg /day	045	22R	-	7.3	9.9	144	4.3	106	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LIP_IND none	A2M ug/mL	A1AGP ug/mL
1	0 µg/day	001	17D	-	Negative	12	68.67
		002	17D	-	Negative	15	52.23
		003	17D	-	Negative	19	24.30
		004	17D	-	Negative	12	34.45
		005	17D	-	Negative	11	43.22
		006	17D	-	Negative	9	60.45
		007	17D	-	Negative	15	53.83
		008	4D	---	Negative	679	948.10
			17D	-	Negative	13	47.23
		009	4D	---	Negative	53	75.58
			17D	-	Negative	19	50.35
		010	4D	---	Negative	44	63.18
			17D	-	Negative	15	41.99
		011	4D	---	Negative	37	75.39
			22R	-	Negative	10	91.41
		012	4D	---	Negative	32	61.74
			22R	-	Negative	9	43.29

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LIP_IND none	A2M ug/mL	A1AGP ug/mL
1	0 µg/day	013	4D	---	Negative	21	48.94
			22R	-	Negative	9	49.54
		014	4D	---	Negative	17	55.88
			22R	-	Negative	6	43.79
		015	4D	---	Negative	24	66.05
			22R	-	Negative	6	46.52
2	30 µg/day	016	17D	-	Negative	1801	2632.51
		017	17D	-	Negative	886	1974.42
		018	17D	-	Negative	576	1817.56
		019	17D	-	Negative	223	1176.32
		020	17D	-	Negative	783	1720.69
		021	17D	-	Negative	2686	2072.64
		022	17D	-	Negative	724	1782.38
		023	4D	---	Negative	1325	1356.32
			17D	-	Negative	395	1845.24
		024	4D	---	Negative	2333	1571.10
			17D	-	Negative	997	1794.51

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LIP_IND none	A2M ug/mL	A1AGP ug/mL
2	30 µg/day	025	4D	---	Negative	1139	1636.32
			17D	-	Negative	835	1543.59
		026	4D	---	Negative	2678	2378.00
			22R	-	Negative	9	66.75
		027	4D	---	Negative	1679	1616.32
			22R	-	Negative	10	69.36
		028	4D	---	Negative	2817	1627.92
			22R	-	Negative	16	55.29
		029	4D	---	Negative	3963	1499.70
			22R	-	Negative	44	65.90
		030	4D	---	Negative	2611	1452.44
			22R	-	Negative	18	121.40
3	30 µg /day	031	17D	-	Negative	2132	2019.27
		032	17D	-	Negative	2439	1495.94
		033	17D	-	Negative	1104	2068.21
		034	17D	-	Negative	1496	1355.49
		035	17D	-	Negative	4973	3485.55

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	HPD	LIP_IND none	A2M ug/mL	A1AGP ug/mL
3	30 µg /day	036	17D	-	Negative	1321	1953.14
		037	17D	-	Negative	1688	2785.50
		038	4D	---	Negative	1370	1538.05
			17D	-	Negative	858	2072.35
		039	4D	---	Negative	4147	1841.85
			17D	-	Negative	1072	1311.89
		040	4D	---	Negative	3404	2437.64
			17D	-	Negative	859	1663.49
		041	4D	---	Negative	1457	1815.29
			22R	-	Negative	15	84.77
		042	4D	---	Negative	10485	4831.95
			22R	-	Negative	19	55.24
		043	4D	---	Negative	4106	2495.36
			22R	-	Negative	17	46.84
		044	4D	---	Negative	2755	1830.75
			22R	-	Negative	13	50.71
		045	4D	---	Negative	3569	2023.44

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Male

Group Number	Dose	Animal	Day	HPD	LIP_IND none	A2M ug/mL	A1AGP ug/mL
3	30 µg /day	045	22R	-	Negative	17	75.25

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	ALT U/L		AST U/L		ALP U/L		GGT U/L		TBIL mg/dL		CHOL mg/dL		TRIG mg/dL	
1	0 µg/day	046	17D	-	12		88		60		<3		<0.1		39		45	
		047	17D	-	9		66		62		<3		<0.1		28		32	
		048	17D	-	12		70		37		<3		<0.1		20		20	
		049	17D	-	11		52		56		<3		<0.1		48		29	
		050	17D	-	11		102		65		<3		<0.1		26		22	
		051	17D	-	11		46		48		<3		0.1		28		22	
		052	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		053	4D	---	26		74		65		<3		<0.1		33		29	
			17D	-	14		75		38		<3		0.1		27		19	
		054	4D	---	28		94		96		<3		<0.1		41		32	
			17D	-	11		78		48		<3		<0.1		30		34	
		055	4D	---	18		64		91		<3		<0.1		72		62	
			17D	-	11		52		44		<3		<0.1		55		27	
		056	4D	---	15		99		94		<3		<0.1		34		32	
			22R	-	10		77		36		3		<0.1		26		22	
		057	4D	---	21		87		84		<3		<0.1		43		25	
			22R	-	15		59		34		<3		0.1		56		40	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	ALT U/L		AST U/L		ALP U/L		GGT U/L		TBIL mg/dL		CHOL mg/dL		TRIG mg/dL	
1	0 µg/day	058	4D	---	20		78		131		<3		<0.1		53		31	
			22R	-	13		61		41		<3		0.1		53		35	
		059	4D	---	21		74		113		<3		<0.1		54		52	
			22R	-	11		59		35		<3		<0.1		47		36	
		060	4D	---	18		84		69		<3		<0.1		35		31	
			22R	-	10		71		24		<3		<0.1		33		21	
2	30 µg/day	061	17D	-	14		96		73		<3		<0.1		41		30	
		062	17D	-	13		88		76		<3		<0.1		33		35	
		063	17D	-	13		71		87		<3		<0.1		34		25	
		064	17D	-	13		81		110		<3		<0.1		24		20	
		065	17D	-	15		96		89		<3		0.1		28		21	
		066	17D	-	10		57		49		<3		<0.1		32		22	
		067	17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	4D	---	29		110		132		<3		<0.1		32		24	
			17D	-	18		103		58		<3		<0.1		29		21	
		069	4D	---	23		90		123		<3		<0.1		47		24	
			17D	-	14		81		80		<3		0.1		42		29	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
2	30 µg/day	070	4D	---	27	79	108	<3	<0.1	63	34
			17D	-	15	62	81	<3	<0.1	40	23
		071	4D	---	20	84	134	<3	<0.1	41	26
			22R	-	14	62	35	<3	0.1	49	33
		072	4D	---	30	120	182	<3	<0.1	68	43
			22R	-	17	82	46	<3	<0.1	75	37
		073	4D	---	20	98	144	<3	<0.1	39	33
			22R	-	12	86	41	<3	<0.1	34	30
		074	4D	---	21	83	135	<3	<0.1	41	24
			22R	-	14	72	31	<3	<0.1	40	32
		075	4D	---	29	105	145	<3	<0.1	47	27
			22R	-	17	66	32	<3	<0.1	73	27
3	30 µg /day	076	17D	-	19	113	118	<3	0.1	33	28
		077	17D	-	- QN	- QN	- QN	- QN	- QN	- QN	- QN
		078	17D	-	15	66	123	<3	0.1	32	22
		079	17D	-	22	86	87	<3	<0.1	31	29
		080	17D	-	13	87	94	<3	<0.1	34	36

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	ALT U/L		AST U/L		ALP U/L		GGT U/L		TBIL mg/dL		CHOL mg/dL		TRIG mg/dL	
3	30 µg /day	081	17D	-	12		52		80		<3		<0.1		23		23	
		082	17D	-	16		71		107		<3		<0.1		30		29	
		083	4D	---	20		85		163		<3		<0.1		71		31	
			17D	-	17		85		102		<3		<0.1		36		25	
		084	4D	---	33		109		157		<3		<0.1		57		46	
			17D	-	18		82		68		<3		<0.1		36		20	
		085	4D	---	21		93		181		<3		<0.1		57		28	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		086	4D	---	29		103		163		<3		<0.1		50		31	
			22R	-	16		70		29		<3		<0.1		44		27	
		087	4D	---	18		93		157		<3		<0.1		39		28	
			22R	-	14		62		37		<3		<0.1		29		37	
		088	4D	---	21		79		125		<3		<0.1		47		28	
			22R	-	13		69		23		<3		<0.1		37		32	
		089	4D	---	23		83		110		<3		<0.1		77		38	
			22R	-	14		72		36		<3		<0.1		52		45	
		090	4D	---	20		85		91		<3		<0.1		55		46	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	ALT U/L	AST U/L	ALP U/L	GGT U/L	TBIL mg/dL	CHOL mg/dL	TRIG mg/dL
3	30 µg /day	090	22R	-	11	63	20	<3	<0.1	44	45

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL		TP g/dL		ALB g/dL		GLOB g/dL		AG none		BUN mg/dL		CREA mg/dL	
1	0 µg/day	046	17D	-	118		4.8		3.3		1.5		2.2		17		0.2	
		047	17D	-	128		5.5		3.7		1.8		2.1		17		0.3	
		048	17D	-	105		5.5		3.5		2.0		1.8		14		0.2	
		049	17D	-	97		5.5		3.6		1.9		1.9		23		0.3	
		050	17D	-	97		5.3		3.5		1.8		1.9		13		0.2	
		051	17D	-	127		5.6		3.7		1.9		1.9		16		0.3	
		052	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		053	4D	---	112		6.6		4.4		2.2		2.0		15		0.3	
			17D	-	83		6.0		4.0		2.0		2.0		15		0.3	
		054	4D	---	94		6.4		4.2		2.2		1.9		17		0.3	
			17D	-	122		5.3		3.5		1.8		1.9		19		0.2	
		055	4D	---	115		6.7		4.5		2.2		2.0		20		0.4	
			17D	-	126		5.5		3.6		1.9		1.9		19		0.4	
		056	4D	---	90		5.6		3.8		1.8		2.1		17		0.3	
			22R	-	108		6.2		4.0		2.2		1.8		17		0.4	
		057	4D	---	101		6.0		4.0		2.0		2.0		19		0.3	
			22R	-	130		6.5		4.4		2.1		2.1		13		0.3	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL		TP g/dL		ALB g/dL		GLOB g/dL		AG none		BUN mg/dL		CREA mg/dL	
1	0 µg/day	058	4D	---	101		6.3		4.2		2.1		2.0		15		0.3	
			22R	-	129		7.1		4.7		2.4		2.0		17		0.4	
		059	4D	---	101		6.4		4.2		2.2		1.9		15		0.3	
			22R	-	130		6.6		4.3		2.3		1.9		21		0.4	
		060	4D	---	106		6.1		4.0		2.1		1.9		16		0.3	
			22R	-	100		6.2		3.9		2.3		1.7		15		0.3	
2	30 µg/day	061	17D	-	90		5.4		3.3		2.1		1.6		20		0.2	
		062	17D	-	111		5.1		3.1		2.0		1.6		20		0.3	
		063	17D	-	98		4.9		3.1		1.8		1.7		23		0.3	
		064	17D	-	106		5.0		3.1		1.9		1.6		22		0.2	
		065	17D	-	89		5.0		3.0		2.0		1.5		16		0.2	
		066	17D	-	107		4.9		3.0		1.9		1.6		14		0.2	
		067	17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	4D	---	72		5.7		3.6		2.1		1.7		16		0.2	
			17D	-	94		4.9		3.0		1.9		1.6		22		0.2	
		069	4D	---	92		5.7		3.6		2.1		1.7		14		0.2	
			17D	-	102		4.6		2.9		1.7		1.7		15		0.2	

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL		TP g/dL		ALB g/dL		GLOB g/dL		AG none		BUN mg/dL		CREA mg/dL	
2	30 µg/day	070	4D	---	94		5.9		3.7		2.2		1.7		25		0.3	
			17D	-	100		5.0		3.1		1.9		1.6		18		0.2	
		071	4D	---	89		5.7		3.6		2.1		1.7		16		0.2	
			22R	-	115		6.8		4.3		2.5		1.7		14		0.3	
		072	4D	---	97		5.6		3.5		2.1		1.7		20		0.2	
			22R	-	98		6.5		4.1		2.4		1.7		18		0.3	
		073	4D	---	97		5.3		3.4		1.9		1.8		17		0.2	
			22R	-	96		6.3		4.0		2.3		1.7		20		0.3	
		074	4D	---	85		5.6		3.5		2.1		1.7		25		0.2	
			22R	-	121		6.7		4.2		2.5		1.7		21		0.3	
		075	4D	---	87		5.7		3.6		2.1		1.7		17		0.3	
			22R	-	108		6.4		4.1		2.3		1.8		19		0.3	
3	30 µg /day	076	17D	-	106		5.4		3.3		2.1		1.6		19		0.3	
		077	17D	-	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN	-	QN
		078	17D	-	90		5.2		3.2		2.0		1.6		21		0.2	
		079	17D	-	107		5.0		3.1		1.9		1.6		20		0.2	
		080	17D	-	88		5.0		3.2		1.8		1.8		20		0.2	

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL		TP g/dL		ALB g/dL		GLOB g/dL		AG none		BUN mg/dL		CREA mg/dL	
3	30 µg /day	081	17D	-	103		4.9		3.0		1.9		1.6		19		0.2	
		082	17D	-	89		4.4		2.9		1.5		1.9		21		0.2	
		083	4D	---	85		5.8		3.6		2.2		1.6		19		0.2	
			17D	-	105		4.9		3.0		1.9		1.6		18		0.2	
		084	4D	---	91		5.7		3.6		2.1		1.7		23		0.2	
			17D	-	108		4.9		3.0		1.9		1.6		22		0.2	
		085	4D	---	88		6.2		3.9		2.3		1.7		19		0.3	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		086	4D	---	75		5.7		3.6		2.1		1.7		14		0.2	
			22R	-	108		6.3		4.1		2.2		1.9		17		0.3	
		087	4D	---	96		5.7		3.6		2.1		1.7		17		0.3	
			22R	-	104		6.8		4.3		2.5		1.7		20		0.3	
		088	4D	---	87		6.1		3.8		2.3		1.7		19		0.3	
			22R	-	95		6.9		4.4		2.5		1.8		20		0.3	
		089	4D	---	87		6.2		3.9		2.3		1.7		18		0.3	
			22R	-	137		7.1		4.6		2.5		1.8		18		0.4	
		090	4D	---	88		6.1		3.8		2.3		1.7		17		0.2	

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	GLUC mg/dL	TP g/dL	ALB g/dL	GLOB g/dL	AG none	BUN mg/dL	CREA mg/dL
3	30 µg /day	090	22R	-	146	6.6	4.2	2.4	1.8	16	0.3

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
1	0 µg/day	046	17D	-	8.2	9.4	144	4.7	109	Negative	Negative
		047	17D	-	8.4	9.4	143	4.0	107	Negative	Negative
		048	17D	-	7.1	9.5	145	4.3	108	Negative	Negative
		049	17D	-	7.2	9.4	145	4.4	108	Negative	Negative
		050	17D	-	7.4	9.5	144	4.8	109	Negative	Negative
		051	17D	-	6.0	9.5	142	4.3	109	Negative	Negative
		052	17D	-	- QN	- QN	- QN	- QN	- QN	- QN	- QN
		053	4D	---	6.2	9.8	144	3.7	104	Negative	Negative
			17D	-	5.9	9.5	144	4.2	108	Negative	Negative
		054	4D	---	7.8	9.9	144	3.7	104	Slight	Negative
			17D	-	8.5	9.7	143	4.6	106	Negative	Negative
		055	4D	---	6.9	10.2	144	3.9	105	Negative	Negative
			17D	-	7.6	9.8	142	4.8	108	Negative	Negative
		056	4D	---	6.3	9.4	142	4.0	103	Negative	Negative
			22R	-	6.1	9.5	143	3.6	107	Negative	Negative
		057	4D	---	6.6	9.5	143	3.8	103	Negative	Negative
			22R	-	7.2	10.1	142	4.0	107	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL		CA mg/dL		NA mmol/L		K mmol/L		CL mmol/L		HEM_IND none		ICT_IND none	
1	0 µg/day	058	4D	---	6.4		9.6		144		3.7		107		Slight		Negative	
			22R	-	7.0		9.9		144		3.8		108		Negative		Negative	
		059	4D	---	6.0		9.7		144		4.0		104		Negative		Negative	
			22R	-	5.3		9.4		139		3.5		103		Negative		Negative	
		060	4D	---	6.7		9.5		145		4.0		103		Slight		Negative	
			22R	-	6.8		9.9		143		4.3		109		Negative		Negative	
2	30 µg/day	061	17D	-	7.4		9.8		144		4.8		106		Negative		Negative	
		062	17D	-	8.1		9.9		144		4.3		110		Slight		Negative	
		063	17D	-	7.0		9.3		144		4.5		109		Negative		Negative	
		064	17D	-	8.3		9.6		142		4.4		106		Negative		Negative	
		065	17D	-	7.3		9.7		141		4.6		106		Negative		Negative	
		066	17D	-	6.7		9.7		143		4.3		110		Negative		Negative	
		067	17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		068	4D	---	7.0		9.5		143		4.4		104		Slight		Negative	
			17D	-	7.2		9.1		145		4.7		109		Negative		Negative	
		069	4D	---	6.0		9.4		144		3.9		107		Negative		Negative	
			17D	-	7.6		9.4		142		4.5		107		Negative		Negative	

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
2	30 µg/day	070	4D	---	6.7	9.5	143	4.6	105	Negative	Negative
			17D	-	6.8	9.3	142	4.7	106	Negative	Negative
		071	4D	---	7.0	9.8	142	4.2	105	Negative	Negative
			22R	-	5.6	9.7	143	3.9	107	Negative	Negative
		072	4D	---	7.3	9.5	142	4.6	101	Negative	Negative
			22R	-	5.4	9.7	142	4.2	104	Slight	Negative
		073	4D	---	5.9	9.4	143	4.2	104	Negative	Negative
			22R	-	6.3	9.8	144	4.1	106	Negative	Negative
		074	4D	---	7.2	9.8	143	4.9	104	Negative	Negative
			22R	-	7.6	10.0	143	4.0	107	Negative	Negative
		075	4D	---	7.4	9.8	145	3.8	106	Negative	Negative
			22R	-	6.6	9.8	144	3.8	106	Negative	Negative
3	30 µg /day	076	17D	-	7.2	9.5	143	4.6	109	Negative	Negative
		077	17D	-	- QN	- QN	- QN	- QN	- QN	- QN	- QN
		078	17D	-	7.8	9.9	143	4.4	108	Negative	Negative
		079	17D	-	9.7	10.0	143	5.2	107	Negative	Negative
		080	17D	-	6.6	9.6	142	4.7	108	Negative	Negative

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL		CA mg/dL		NA mmol/L		K mmol/L		CL mmol/L		HEM_IND none		ICT_IND none	
3	30 µg /day	081	17D	-	6.9		9.6		144		4.6		110		Negative		Negative	
		082	17D	-	8.0		9.2		144		4.8		109		Negative		Negative	
		083	4D	---	6.7		10.0		142		4.4		105		Negative		Negative	
			17D	-	8.6		9.9		142		4.9		106		Slight		Negative	
		084	4D	---	6.9		10.1		144		4.8		105		Negative		Negative	
			17D	-	7.0		9.5		144		4.8		108		Slight		Negative	
		085	4D	---	6.2		9.7		146		4.2		107		Negative		Negative	
			17D	-	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS	-	NS
		086	4D	---	6.6		9.3		143		4.1		103		Negative		Negative	
			22R	-	7.8		9.5		144		4.0		107		Negative		Negative	
		087	4D	---	8.1		9.5		145		3.8		108		Negative		Negative	
			22R	-	7.0		9.8		144		3.7		106		Negative		Negative	
		088	4D	---	6.9		10.1		144		4.7		107		Negative		Negative	
			22R	-	6.1		9.9		143		4.1		108		Negative		Negative	
		089	4D	---	6.6		9.9		142		4.8		103		Negative		Negative	
			22R	-	7.4		10.3		142		3.9		106		Negative		Negative	
		090	4D	---	7.3		9.9		144		4.3		103		Slight		Negative	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	PHOS mg/dL	CA mg/dL	NA mmol/L	K mmol/L	CL mmol/L	HEM_IND none	ICT_IND none
3	30 µg /day	090	22R	-	5.5	9.6	141	4.3	107	Negative	Negative

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LIP_IND none		A2M ug/mL	A1AGP ug/mL
1	0 µg/day	046	17D	-	Negative		33	94.42
		047	17D	-	Negative		22	80.84
		048	17D	-	Negative		173	328.40
		049	17D	-	Negative		15	71.66
		050	17D	-	Negative		10	80.68
		051	17D	-	Negative		26	69.19
		052	17D	-	-	QN	13	49.83
		053	4D	---	Negative		211	287.21
			17D	-	Negative		18	54.31
		054	4D	---	Negative		530	391.89
			17D	-	Negative		11	67.97
		055	4D	---	Negative		612	582.86
			17D	-	Negative		10	62.29
		056	4D	---	Negative		22	72.80
			22R	-	Negative		16	84.10
		057	4D	---	Negative		20	165.20
			22R	-	Negative		11	54.10

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LIP_IND none		A2M ug/mL		A1AGP ug/mL	
1	0 µg/day	058	4D	---	Negative		255		220.09	
			22R	-	Negative		32		48.05	
		059	4D	---	Negative		29		77.14	
			22R	-	Negative		15		45.77	
		060	4D	---	Negative		18		121.00	
			22R	-	Negative		12		81.92	
2	30 µg/day	061	17D	-	Negative		948		1837.15	
		062	17D	-	Negative		599		1641.31	
		063	17D	-	Negative		249		1335.38	
		064	17D	-	Negative		796		1360.18	
		065	17D	-	Negative		405		1320.56	
		066	17D	-	Negative		260		1397.00	
		067	17D	-	-	NS	-	NS	-	NS
		068	4D	---	Negative		1214		1990.76	
			17D	-	Negative		484		1043.02	
		069	4D	---	Negative		255		1426.67	
			17D	-	Negative		231		1358.38	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LIP_IND none		A2M ug/mL		A1AGP ug/mL	
2	30 µg/day	070	4D	---	Negative		511		1993.04	
			17D	-	Negative		717		2133.66	
		071	4D	---	Negative		966		1716.82	
			22R	-	Negative		14		26.72	
		072	4D	---	Negative		1231		2125.32	
			22R	-	Negative		15		53.78	
		073	4D	---	Negative		289		1471.09	
			22R	-	Negative		11		46.76	
		074	4D	---	Negative		744		1933.38	
			22R	-	Negative		26		53.28	
		075	4D	---	Negative		420		2593.43	
			22R	-	Negative		15		59.02	
3	30 µg /day	076	17D	-	Negative		989		2110.38	
		077	17D	-	-	QN	-	QN	-	QN
		078	17D	-	Negative		953		1992.92	
		079	17D	-	Negative		530		1837.66	
		080	17D	-	Negative		399		1607.53	

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Clinical Chemistry

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LIP_IND none		A2M ug/mL		A1AGP ug/mL	
3	30 µg /day	081	17D	-	Negative		447		1295.34	
		082	17D	-	Negative		588		855.25	
		083	4D	---	Negative		1178		2088.91	
			17D	-	Negative		377		1754.23	
		084	4D	---	Negative		597		1882.91	
			17D	-	Negative		453		1755.26	
		085	4D	---	Negative		886		1606.16	
			17D	-	-	NS	-	NS	-	NS
		086	4D	---	Negative		883		1965.13	
			22R	-	Negative		16		39.63	
		087	4D	---	Negative		563		1350.77	
			22R	-	Negative		22		73.06	
		088	4D	---	Negative		606		1429.46	
			22R	-	Negative		18		34.16	
		089	4D	---	Negative		1600		1484.34	
			22R	-	Negative		13		63.68	
		090	4D	---	Negative		784		1609.14	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	HPD	LIP_IND none	A2M ug/mL	A1AGP ug/mL
3	30 µg /day	090	22R	-	Negative	11	77.41

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Appendix 9

Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Parameter	Description
COLOR	Color
CLARITY	Clarity
pH	pH
GLU	Glucose Urine
KET	Ketones
PRO	Protein
BIL	Bilirubin
BLOOD	Blood
SG	Specific Gravity
VOLUME	Total Volume
F_ELEM	Formed Elements
U_RBC	RBC, Urine
U_WBC	WBC, Urine
SQ_EPI	Epithelial Cells, Squamous
TR_PHOS	Crystal, Triple Phosphate
SPERM	Sperm

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

- Value not applicable;

Note: Each interval/day will be concatenated with the phase name abbreviation

HPD = Hours Post Dose; U = Unscheduled

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Appendix 9

Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	COLOR none	CLARITY none	pH none	GLU mg/dL	KET mg/dL	PRO mg/dL	BIL none	BLOOD none
1	0 µg/day	001	17D	Dark Yellow	Clear	7.5	Negative	15	30	Negative	Negative
		002	17D	Dark Yellow	Clear	6.5	Negative	15	30	Negative	Negative
		003	17D	Dark Yellow	Cloudy	7.0	Negative	15	30	Negative	Negative
		004	17D	Yellow	Clear	7.0	Negative	Trace	Trace	Negative	Negative
		005	17D	Dark Yellow	Clear	6.5	Negative	15	30	Negative	Negative
		006	17D	Yellow	Clear	7.5	Negative	Trace	Negative	Negative	Negative
		007	17D	Yellow	Clear	7.5	Negative	Negative	Negative	Negative	Negative
		008	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		009	17D	Dark Yellow	Cloudy	7.0	Negative	15	100	Negative	Negative
		010	17D	Dark Yellow	Clear	7.5	Negative	Trace	30	Negative	Negative
		011	22R	Dark Yellow	Cloudy	7.0	Negative	15	30	Negative	Negative
		012	22R	Dark Yellow	Clear	7.0	Negative	15	30	Negative	Negative
		013	22R	Dark Yellow	Clear	7.5	Negative	15	30	Negative	Negative
		014	22R	Dark Yellow	Clear	7.0	Negative	15	30	Negative	Negative
		015	22R	Dark Yellow	Clear	8.0	Negative	15	30	Negative	Negative
2	30 µg/day	016	17D	Yellow	Clear	6.5	Negative	Trace	Trace	Negative	Negative
		017	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		018	17D	Dark Yellow	Cloudy	6.5	Negative	Trace	100	Negative	Negative
		019	17D	Yellow	Clear	7.0	Negative	Trace	Trace	Negative	Negative
		020	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	COLOR none	CLARITY none	pH none	GLU mg/dL	KET mg/dL	PRO mg/dL	BIL none	BLOOD none
2	30 µg/day	021	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		022	17D	Dark Yellow	Cloudy	6.0	Negative	15	100	Small	Negative
		023	17D	Yellow	Clear	7.0	Negative	Trace	Trace	Negative	Negative
		024	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		025	17D	Yellow	Clear	7.0	Negative	Trace	Negative	Negative	Negative
		026	22R	Dark Yellow	Clear	7.0	Negative	15	30	Negative	Negative
		027	22R	Yellow	Clear	7.5	Negative	Trace	Trace	Negative	Negative
		028	22R	Yellow	Clear	7.0	Negative	Trace	Trace	Negative	Negative
		029	22R	Dark Yellow	Clear	7.5	Negative	15	30	Negative	Negative
		030	22R	Yellow	Clear	7.0	Negative	15	30	Negative	Negative
3	30 µg /day	031	17D	Dark Yellow	Clear	6.5	Negative	15	30	Negative	Negative
		032	17D	Yellow	Clear	7.0	Negative	Trace	Trace	Negative	Negative
		033	17D	Dark Yellow	Cloudy	6.0	Negative	Trace	100	Small	Negative
		034	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		035	17D	Yellow	Clear	6.5	Negative	Trace	30	Negative	Negative
		036	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		037	17D	Yellow	Clear	6.5	Negative	Trace	Trace	Negative	Negative
		038	17D	Dark Yellow	Clear	6.5	Negative	Trace	30	Negative	Negative
		039	17D	Yellow	Clear	6.5	Negative	Trace	Negative	Negative	Negative
		040	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	COLOR none	CLARITY none	pH none	GLU mg/dL	KET mg/dL	PRO mg/dL	BIL none	BLOOD none
3	30 µg /day	041	22R	Dark Yellow	Cloudy	7.0	Negative	15	30	Negative	Negative
		042	22R	Yellow	Clear	7.5	Negative	Negative	Negative	Negative	Negative
		043	22R	Dark Yellow	Clear	7.0	Negative	40	100	Negative	Negative
		044	22R	Dark Yellow	Clear	6.5	Negative	15	30	Negative	Negative
		045	22R	Yellow	Clear	7.0	Negative	Trace	30	Negative	Negative

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	SG none	VOLUME mL	F_ELEM none	U_RBC /HPF	U_WBC /HPF	SQ_EPI /LPF	TR_PHOS /HPF	SPERM none
1	0 µg/day	001	17D	1.035	7.0	Reported	-	-	-	Many	Present
		002	17D	1.049	5.0	Reported	-	-	0-5	-	Present
		003	17D	1.043	6.0	Reported	-	0-5	0-5	Moderate	Present
		004	17D	1.016	16.0	Reported	-	-	0-5	-	Present
		005	17D	1.047	5.0	Reported	-	-	0-5	-	Present
		006	17D	1.013	17.0	-	-	-	-	-	-
		007	17D	1.008	37.0	-	-	-	-	-	-
		008	17D	1.006	48.0	-	-	-	-	-	-
		009	17D	1.067	2.0	-	-	-	-	-	-
		010	17D	1.038	6.0	-	-	-	-	-	-
		011	22R	1.051	3.0	Reported	-	-	0-5	Moderate	Present
		012	22R	1.059	4.5	Reported	-	0-5	0-5	Few	Present
		013	22R	1.057	3.0	Reported	0-5	-	0-5	Few	Present
		014	22R	1.059	3.0	Reported	-	-	0-5	Few	Present
		015	22R	1.052	5.0	Reported	-	0-5	0-5	Moderate	Present
2	30 µg/day	016	17D	1.020	13.0	Reported	-	0-5	0-5	Few	Present
		017	17D	1.013	17.0	Reported	-	-	0-5	-	Present
		018	17D	1.063	3.0	Reported	-	-	0-5	Many	-
		019	17D	1.029	9.0	Reported	-	-	-	Few	Present
		020	17D	1.007	28.0	Reported	-	-	0-5	-	Present

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	SG none	VOLUME mL	F_ELEM none	U_RBC /HPF	U_WBC /HPF	SQ_EPI /LPF	TR_PHOS /HPF	SPERM none
2	30 µg/day	021	17D	1.005	60.0	-	-	-	-	-	-
		022	17D	1.070	2.0	-	-	-	-	-	-
		023	17D	1.025	8.0	-	-	-	-	-	-
		024	17D	1.011	23.0	-	-	-	-	-	-
		025	17D	1.017	15.0	-	-	-	-	-	-
		026	22R	1.048	4.0	Reported	0-5	-	-	Few	Present
		027	22R	1.026	10.0	Reported	-	0-5	0-5	Few	Present
		028	22R	1.013	17.0	Reported	-	0-5	0-5	-	Present
		029	22R	1.046	4.0	Reported	-	0-5	0-5	Moderate	Present
		030	22R	1.037	6.0	Reported	0-5	0-5	0-5	Few	Present
3	30 µg /day	031	17D	1.056	3.0	Reported	-	-	0-5	Few	Present
		032	17D	1.023	9.0	Reported	-	0-5	0-5	Few	Present
		033	17D	1.060	3.0	Reported	-	0-5	0-5	Few	Present
		034	17D	1.013	20.0	Reported	-	-	0-5	-	Present
		035	17D	1.022	9.0	Reported	-	-	0-5	Few	Present
		036	17D	1.016	17.0	-	-	-	-	-	-
		037	17D	1.020	13.0	-	-	-	-	-	-
		038	17D	1.045	5.0	-	-	-	-	-	-
		039	17D	1.014	15.0	-	-	-	-	-	-
		040	17D	1.013	22.0	-	-	-	-	-	-

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal	Day	SG none	VOLUME mL	F_ELEM none	U_RBC /HPF	U_WBC /HPF	SQ_EPI /LPF	TR_PHOS /HPF	SPERM none
3	30 µg /day	041	22R	1.057	3.0	Reported	-	0-5	0-5	Moderate	Present
		042	22R	1.011	27.0	Reported	-	0-5	0-5	-	Present
		043	22R	1.070	2.0	Reported	-	0-5	0-5	Few	Present
		044	22R	1.052	3.0	Reported	-	0-5	0-5	Moderate	Present
		045	22R	1.030	5.0	Reported	-	-	0-5	Few	Present

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	COLOR none	CLARITY none	pH none	GLU mg/dL	KET mg/dL	PRO mg/dL	BIL none	BLOOD none
1	0 µg/day	046	17D	Dark Yellow	Clear	6.5	Negative	Trace	Negative	Negative	Negative
		047	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		048	17D	Dark Yellow	Clear	6.5	Negative	Negative	Trace	Negative	Negative
		049	17D	Yellow	Clear	7.0	Negative	Negative	Trace	Negative	Negative
		050	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		051	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		052	17D	Dark Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		053	17D	Dark Yellow	Clear	6.5	Negative	Trace	Trace	Negative	Negative
		054	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		055	17D	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		056	22R	Yellow	Clear	7.0	Negative	Trace	Trace	Negative	Negative
		057	22R	Yellow	Clear	7.0	Negative	Negative	Negative	Negative	Negative
		058	22R	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		059	22R	Dark Yellow	Clear	6.5	Negative	Trace	Trace	Negative	Negative
		060	22R	Yellow	Clear	8.0	Negative	Negative	Negative	Negative	Negative
2	30 µg/day	061	17D	Dark Yellow	Clear	6.0	Negative	Negative	Trace	Negative	Negative
		062	17D	Dark Yellow	Clear	6.0	Negative	Trace	Trace	Negative	Negative
		063	17D	Dark Yellow	Clear	6.0	Negative	Trace	30	Negative	Negative
		064	17D	Yellow	Clear	6.0	Negative	Negative	Negative	Negative	Negative
		065	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	COLOR none	CLARITY none	pH none	GLU mg/dL	KET mg/dL	PRO mg/dL	BIL none	BLOOD none
2	30 µg/day	066	17D	Dark Yellow	Clear	6.5	Negative	Negative	Trace	Negative	Negative
		067	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		068	17D	Dark Yellow	Clear	6.0	Negative	Negative	Trace	Negative	Negative
		069	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		070	17D	Dark Yellow	Cloudy	6.0	Negative	Negative	Trace	Negative	Negative
		071	22R	Dark Yellow	Clear	6.5	Negative	Trace	Trace	Negative	Negative
		072	22R	Yellow	Clear	6.0	Negative	Negative	Negative	Negative	Negative
		073	22R	Dark Yellow	Clear	7.0	Negative	15	30	Negative	Negative
		074	22R	Yellow	Clear	7.5	Negative	Negative	Negative	Negative	Negative
		075	22R	Dark Yellow	Clear	6.0	Negative	Trace	Trace	Negative	Negative
3	30 µg /day	076	17D	Dark Yellow	Clear	6.5	Negative	Negative	Trace	Negative	Negative
		077	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		078	17D	Dark Yellow	Clear	6.5	Negative	Trace	30	Negative	Negative
		079	17D	Yellow	Clear	6.0	Negative	Trace	Trace	Negative	Negative
		080	17D	Yellow	Clear	6.0	Negative	Negative	Negative	Negative	Negative
		081	17D	Dark Yellow	Cloudy	6.0	Negative	Trace	30	Negative	Negative
		082	17D	Yellow	Clear	6.0	Negative	Negative	Negative	Negative	Negative
		083	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		084	17D	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		085	17D	Dark Yellow	Clear	5.5	Negative	Negative	30	Negative	Negative

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	COLOR none	CLARITY none	pH none	GLU mg/dL	KET mg/dL	PRO mg/dL	BIL none	BLOOD none
3	30 µg /day	086	22R	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		087	22R	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative
		088	22R	Dark Yellow	Clear	7.0	Negative	Trace	30	Negative	Negative
		089	22R	Dark Yellow	Clear	6.0	Negative	Negative	Trace	Negative	Negative
		090	22R	Yellow	Clear	6.5	Negative	Negative	Negative	Negative	Negative

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	SG none	VOLUME mL	F_ELEM none	U_RBC /HPF	U_WBC /HPF	SQ_EPI /LPF	TR_PHOS /HPF
1	0 µg/day	046	17D	1.035	5.0	Reported	-	0-5	0-5	Few
		047	17D	1.024	8.0	Reported	-	-	0-5	Few
		048	17D	1.035	4.0	Reported	-	-	0-5	-
		049	17D	1.033	5.0	Reported	-	0-5	0-5	Few
		050	17D	1.010	17.0	Reported	-	-	0-5	-
		051	17D	1.015	12.0	-	-	-	-	-
		052	17D	1.029	5.0	-	-	-	-	-
		053	17D	1.044	4.0	-	-	-	-	-
		054	17D	1.011	14.0	-	-	-	-	-
		055	17D	1.007	25.0	-	-	-	-	-
		056	22R	1.042	3.0	Reported	-	0-5	0-5	-
		057	22R	1.011	18.0	Reported	0-5	0-5	0-5	-
		058	22R	1.010	15.0	Reported	-	0-5	0-5	-
		059	22R	1.044	3.0	Reported	0-5	0-5	0-5	Few
		060	22R	1.013	16.0	Reported	-	0-5	0-5	-
2	30 µg/day	061	17D	1.046	4.0	Reported	-	-	0-5	-
		062	17D	1.037	2.0	Reported	-	0-5	0-5	-
		063	17D	1.054	2.0	Reported	-	-	0-5	Few
		064	17D	1.008	26.0	Reported	-	-	0-5	-
		065	17D	1.014	12.0	Reported	-	0-5	0-5	-

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	SG none	VOLUME mL	F_ELEM none	U_RBC /HPF	U_WBC /HPF	SQ_EPI /LPF	TR_PHOS /HPF
2	30 µg/day	066	17D	1.036	4.0	-	-	-	-	-
		067	17D	1.011	17.0	-	-	-	-	-
		068	17D	1.034	4.0	-	-	-	-	-
		069	17D	1.011	22.0	-	-	-	-	-
		070	17D	1.037	3.0	-	-	-	-	-
		071	22R	1.044	3.5	Reported	0-5	0-5	0-5	-
		072	22R	1.016	14.0	Reported	-	0-5	0-5	-
		073	22R	1.059	1.5	Reported	-	0-5	0-5	Few
		074	22R	1.021	8.0	Reported	-	0-5	0-5	Few
		075	22R	1.042	3.0	Reported	-	0-5	0-5	-
3	30 µg /day	076	17D	1.033	3.0	Reported	-	-	0-5	Few
		077	17D	1.011	20.0	Reported	-	0-5	0-5	-
		078	17D	1.035	4.0	Reported	-	0-5	0-5	-
		079	17D	1.028	5.0	Reported	-	0-5	0-5	-
		080	17D	1.010	16.0	Reported	-	-	0-5	-
		081	17D	1.038	3.0	-	-	-	-	-
		082	17D	1.025	7.0	-	-	-	-	-
		083	17D	1.011	15.0	-	-	-	-	-
		084	17D	1.010	18.0	-	-	-	-	-
		085	17D	1.049	3.0	-	-	-	-	-

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Urinalysis

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal	Day	SG none	VOLUME mL	F_ELEM none	U_RBC /HPF	U_WBC /HPF	SQ_EPI /LPF	TR_PHOS /HPF
3	30 µg /day	086	22R	1.009	20.0	Reported	-	0-5	0-5	-
		087	22R	1.021	8.0	Reported	-	0-5	0-5	Few
		088	22R	1.055	1.5	Reported	-	0-5	0-5	Few
		089	22R	1.041	3.0	Reported	-	0-5	0-5	-
		090	22R	1.012	12.5	Reported	-	0-5	0-5	-

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

- = Value not applicable; NW = Not Weighed; e = Excluded.
ABS = Absolute Value; OW = Organ Weight; BW = Body Weight; BRN = Brain Weight;
OW:BW = (g/g)*100; OW:BRN = g/g.

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Brain			Epididymis			Gland, Adrenal		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
1	0 µg/day	001	Dosing-Terminal Euthanasia	269.7	1.834	0.680	1.000	1.242	0.461	0.677	0.070	0.026	0.038
		002	Dosing-Terminal Euthanasia	321.3	1.931	0.601	1.000	1.522	0.474	0.788	0.083	0.026	0.043
		003	Dosing-Terminal Euthanasia	300.0	1.951	0.650	1.000	1.275	0.425	0.654	0.077	0.026	0.039
		004	Dosing-Terminal Euthanasia	315.7	2.098	0.665	1.000	1.224	0.388	0.583	0.063	0.020	0.030
		005	Dosing-Terminal Euthanasia	294.1	1.928	0.656	1.000	1.211	0.412	0.628	0.071	0.024	0.037
		006	Dosing-Terminal Euthanasia	304.8	1.851	0.607	1.000	1.018	0.334	0.550	0.066	0.022	0.036
		007	Dosing-Terminal Euthanasia	304.1	1.894	0.623	1.000	0.907	0.298	0.479	0.073	0.024	0.039
		008	Dosing-Terminal Euthanasia	286.7	1.760	0.614	1.000	1.136	0.396	0.645	0.070	0.024	0.040
		009	Dosing-Terminal Euthanasia	276.4	1.946	0.704	1.000	1.066	0.386	0.548	0.062	0.022	0.032
		010	Dosing-Terminal Euthanasia	287.8	1.868	0.649	1.000	1.046	0.363	0.560	0.062	0.022	0.033
		011	Recovery-Recovery Euthanasia 1	329.10	2.173	0.660	1.000	1.454	0.442	0.669	0.065	0.020	0.030
		012	Recovery-Recovery Euthanasia 1	362.80	2.080	0.573	1.000	1.522	0.420	0.732	0.062	0.017	0.030
		013	Recovery-Recovery Euthanasia 1	304.00	2.098	0.690	1.000	1.216	0.400	0.580	0.072	0.024	0.034
		014	Recovery-Recovery Euthanasia 1	283.80	2.052	0.723	1.000	1.341	0.473	0.654	0.053	0.019	0.026
		015	Recovery-Recovery Euthanasia 1	379.20	2.133	0.563	1.000	1.268	0.334	0.594	0.083	0.022	0.039

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Brain			Epididymis			Gland, Adrenal		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
2	30 µg/day	016	Dosing-Terminal Euthanasia	257.4	1.765	0.686	1.000	1.055	0.410	0.598	0.072	0.028	0.041
		017	Dosing-Terminal Euthanasia	284.4	1.949	0.685	1.000	0.885	0.311	0.454	0.066	0.023	0.034
		018	Dosing-Terminal Euthanasia	267.3	1.839	0.688	1.000	0.878	0.328	0.477	0.061	0.023	0.033
		019	Dosing-Terminal Euthanasia	289.1	1.772	0.613	1.000	1.129	0.391	0.637	0.099	0.034	0.056
		020	Dosing-Terminal Euthanasia	250.2	2.006	0.802	1.000	1.105	0.442	0.551	0.062	0.025	0.031
		021	Dosing-Terminal Euthanasia	269.6	2.062	0.765	1.000	1.058	0.392	0.513	0.068	0.025	0.033
		022	Dosing-Terminal Euthanasia	268.5	1.746	0.650	1.000	1.162	0.433	0.666	0.064	0.024	0.037
		023	Dosing-Terminal Euthanasia	274.5	1.830	0.667	1.000	1.119	0.408	0.611	0.095	0.035	0.052
		024	Dosing-Terminal Euthanasia	248.5	2.033	0.818	1.000	0.949	0.382	0.467	0.056	0.023	0.028
		025	Dosing-Terminal Euthanasia	302.2	2.157	0.714	1.000	1.286	0.426	0.596	0.084	0.028	0.039
		026	Recovery-Recovery Euthanasia 1	351.50	1.815	0.516	1.000	1.131	0.322	0.623	0.068	0.019	0.037
		027	Recovery-Recovery Euthanasia 1	340.00	1.818	0.535	1.000	1.023	0.301	0.563	0.078	0.023	0.043
		028	Recovery-Recovery Euthanasia 1	335.40	2.080	0.620	1.000	1.310	0.391	0.630	0.115	0.034	0.055
		029	Recovery-Recovery Euthanasia 1	350.40	2.062	0.588	1.000	1.259	0.359	0.611	0.101	0.029	0.049
		030	Recovery-Recovery Euthanasia 1	380.20	2.020	0.531	1.000	1.550	0.408	0.767	0.090	0.024	0.045

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Brain			Epididymis			Gland, Adrenal		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
3	30 µg /day	031	Dosing-Terminal Euthanasia	244.7	1.808	0.739	1.000	1.116	0.456	0.617	0.075	0.031	0.041
		032	Dosing-Terminal Euthanasia	254.6	1.897	0.745	1.000	1.083	0.425	0.571	0.052	0.020	0.027
		033	Dosing-Terminal Euthanasia	301.1	1.945	0.646	1.000	0.970	0.322	0.499	0.077	0.026	0.040
		034	Dosing-Terminal Euthanasia	250.4	1.842	0.736	1.000	1.087	0.434	0.590	0.074	0.030	0.040
		035	Dosing-Terminal Euthanasia	235.8	1.922	0.815	1.000	1.018	0.432	0.530	0.081	0.034	0.042
		036	Dosing-Terminal Euthanasia	278.8	1.898	0.681	1.000	1.025	0.368	0.540	0.085	0.030	0.045
		037	Dosing-Terminal Euthanasia	273.2	1.861	0.681	1.000	0.953	0.349	0.512	0.077	0.028	0.041
		038	Dosing-Terminal Euthanasia	258.7	1.951	0.754	1.000	1.006	0.389	0.516	0.062	0.024	0.032
		039	Dosing-Terminal Euthanasia	262.2	1.947	0.743	1.000	1.159	0.442	0.595	0.064	0.024	0.033
		040	Dosing-Terminal Euthanasia	266.4	2.011	0.755	1.000	1.091	0.410	0.543	0.059	0.022	0.029
		041	Recovery-Recovery Euthanasia 1	339.00	1.922	0.567	1.000	1.394	0.411	0.725	0.069	0.020	0.036
		042	Recovery-Recovery Euthanasia 1	325.50	1.962	0.603	1.000	1.433	0.440	0.730	0.063	0.019	0.032
		043	Recovery-Recovery Euthanasia 1	344.20	1.939	0.563	1.000	1.401	0.407	0.723	0.070	0.020	0.036
		044	Recovery-Recovery Euthanasia 1	347.50	1.938	0.558	1.000	1.472	0.424	0.760	0.083	0.024	0.043
		045	Recovery-Recovery Euthanasia 1	315.60	1.943	0.616	1.000	1.302	0.413	0.670	0.099	0.031	0.051

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Gland, Prostate			Heart			Kidney		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
1	0 µg/day	001	Dosing-Terminal Euthanasia	269.7	0.704	0.261	0.384	0.946	0.351	0.516	1.935	0.717	1.055
		002	Dosing-Terminal Euthanasia	321.3	0.834	0.260	0.432	0.900	0.280	0.466	2.224	0.692	1.152
		003	Dosing-Terminal Euthanasia	300.0	0.799	0.266	0.410	0.925	0.308	0.474	2.439	0.813	1.250
		004	Dosing-Terminal Euthanasia	315.7	0.867	0.275	0.413	0.962	0.305	0.459	2.388	0.756	1.138
		005	Dosing-Terminal Euthanasia	294.1	0.766	0.260	0.397	0.879	0.299	0.456	2.197	0.747	1.140
		006	Dosing-Terminal Euthanasia	304.8	0.589	0.193	0.318	0.915	0.300	0.494	2.216	0.727	1.197
		007	Dosing-Terminal Euthanasia	304.1	0.585	0.192	0.309	1.053	0.346	0.556	2.288	0.752	1.208
		008	Dosing-Terminal Euthanasia	286.7	0.756	0.264	0.430	0.890	0.310	0.506	1.900	0.663	1.080
		009	Dosing-Terminal Euthanasia	276.4	0.724	0.262	0.372	0.906	0.328	0.466	2.042	0.739	1.049
		010	Dosing-Terminal Euthanasia	287.8	0.591	0.205	0.316	0.776	0.270	0.415	2.030	0.705	1.087
		011	Recovery-Recovery Euthanasia 1	329.10	0.884	0.269	0.407	1.011	0.307	0.465	2.406	0.731	1.107
		012	Recovery-Recovery Euthanasia 1	362.80	1.159	0.319	0.557	1.124	0.310	0.540	2.724	0.751	1.310
		013	Recovery-Recovery Euthanasia 1	304.00	1.450	0.477	0.691	0.790	0.260	0.377	2.060	0.678	0.982
		014	Recovery-Recovery Euthanasia 1	283.80	0.874	0.308	0.426	0.898	0.316	0.438	2.025	0.714	0.987
		015	Recovery-Recovery Euthanasia 1	379.20	1.299	0.343	0.609	1.311	0.346	0.615	2.814	0.742	1.319

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Gland, Prostate			Heart			Kidney		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
2	30 µg/day	016	Dosing-Terminal Euthanasia	257.4	0.697	0.271	0.395	0.964	0.375	0.546	1.965	0.763	1.113
		017	Dosing-Terminal Euthanasia	284.4	0.479	0.168	0.246	0.934	0.328	0.479	2.181	0.767	1.119
		018	Dosing-Terminal Euthanasia	267.3	0.520	0.195	0.283	0.801	0.300	0.436	2.195	0.821	1.194
		019	Dosing-Terminal Euthanasia	289.1	0.772	0.267	0.436	1.180	0.408	0.666	2.352	0.814	1.327
		020	Dosing-Terminal Euthanasia	250.2	0.658	0.263	0.328	0.880	0.352	0.439	2.020	0.807	1.007
		021	Dosing-Terminal Euthanasia	269.6	0.636	0.236	0.308	0.968	0.359	0.469	2.323	0.862	1.127
		022	Dosing-Terminal Euthanasia	268.5	0.683	0.254	0.391	0.838	0.312	0.480	2.064	0.769	1.182
		023	Dosing-Terminal Euthanasia	274.5	0.716	0.261	0.391	0.894	0.326	0.489	2.163	0.788	1.182
		024	Dosing-Terminal Euthanasia	248.5	0.950	0.382	0.467	0.785	0.316	0.386	2.182	0.878	1.073
		025	Dosing-Terminal Euthanasia	302.2	1.213	0.401	0.562	0.998	0.330	0.463	2.752	0.911	1.276
		026	Recovery-Recovery Euthanasia 1	351.50	0.869	0.247	0.479	1.038	0.295	0.572	2.282	0.649	1.257
		027	Recovery-Recovery Euthanasia 1	340.00	1.029	0.303	0.566	1.043	0.307	0.574	2.270	0.668	1.249
		028	Recovery-Recovery Euthanasia 1	335.40	1.306	0.389	0.628	1.152	0.343	0.554	2.440	0.727	1.173
		029	Recovery-Recovery Euthanasia 1	350.40	0.884	0.252	0.429	1.171	0.334	0.568	2.364	0.675	1.146
		030	Recovery-Recovery Euthanasia 1	380.20	1.008	0.265	0.499	1.091	0.287	0.540	2.347	0.617	1.162

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Gland, Prostate			Heart			Kidney		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
3	30 µg /day	031	Dosing-Terminal Euthanasia	244.7	0.709	0.290	0.392	0.807	0.330	0.446	1.808	0.739	1.000
		032	Dosing-Terminal Euthanasia	254.6	0.580	0.228	0.306	0.805	0.316	0.424	1.998	0.785	1.053
		033	Dosing-Terminal Euthanasia	301.1	0.781	0.259	0.402	0.984	0.327	0.506	2.209	0.734	1.136
		034	Dosing-Terminal Euthanasia	250.4	0.500	0.200	0.271	0.837	0.334	0.454	1.720	0.687	0.934
		035	Dosing-Terminal Euthanasia	235.8	0.724	0.307	0.377	0.767	0.325	0.399	1.828	0.775	0.951
		036	Dosing-Terminal Euthanasia	278.8	0.767	0.275	0.404	0.898	0.322	0.473	2.325	0.834	1.225
		037	Dosing-Terminal Euthanasia	273.2	0.651	0.238	0.350	1.127	0.413	0.606	2.067	0.757	1.111
		038	Dosing-Terminal Euthanasia	258.7	0.545	0.211	0.279	0.853	0.330	0.437	2.221	0.859	1.138
		039	Dosing-Terminal Euthanasia	262.2	0.836	0.319	0.429	0.853	0.325	0.438	1.981	0.756	1.017
		040	Dosing-Terminal Euthanasia	266.4	0.662	0.248	0.329	0.864	0.324	0.430	2.095	0.786	1.042
		041	Recovery-Recovery Euthanasia 1	339.00	0.909	0.268	0.473	1.091	0.322	0.568	2.470	0.729	1.285
		042	Recovery-Recovery Euthanasia 1	325.50	0.823	0.253	0.419	0.958	0.294	0.488	1.963	0.603	1.001
		043	Recovery-Recovery Euthanasia 1	344.20	1.169	0.340	0.603	1.085	0.315	0.560	2.293	0.666	1.183
		044	Recovery-Recovery Euthanasia 1	347.50	1.088	0.313	0.561	1.088	0.313	0.561	2.331	0.671	1.203
		045	Recovery-Recovery Euthanasia 1	315.60	1.234	0.391	0.635	1.104	0.350	0.568	2.359	0.747	1.214

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Liver			Spleen			Testis		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
1	0 µg/day	001	Dosing-Terminal Euthanasia	269.7	8.285	3.072	4.517	0.503	0.187	0.274	3.436	1.274	1.874
		002	Dosing-Terminal Euthanasia	321.3	9.334	2.905	4.834	0.669	0.208	0.346	3.283	1.022	1.700
		003	Dosing-Terminal Euthanasia	300.0	8.844	2.948	4.533	0.598	0.199	0.307	3.689	1.230	1.891
		004	Dosing-Terminal Euthanasia	315.7	8.552	2.709	4.076	0.689	0.218	0.328	3.599	1.140	1.715
		005	Dosing-Terminal Euthanasia	294.1	8.495	2.888	4.406	0.604	0.205	0.313	3.500	1.190	1.815
		006	Dosing-Terminal Euthanasia	304.8	8.099	2.657	4.375	0.537	0.176	0.290	2.828	0.928	1.528
		007	Dosing-Terminal Euthanasia	304.1	8.327	2.738	4.397	0.635	0.209	0.335	2.729	0.897	1.441
		008	Dosing-Terminal Euthanasia	286.7	7.583	2.645	4.309	0.607	0.212	0.345	3.189	1.112	1.812
		009	Dosing-Terminal Euthanasia	276.4	7.937	2.872	4.079	0.590	0.213	0.303	3.296	1.192	1.694
		010	Dosing-Terminal Euthanasia	287.8	7.762	2.697	4.155	0.519	0.180	0.278	3.178	1.104	1.701
		011	Recovery-Recovery Euthanasia 1	329.10	8.169	2.482	3.759	0.602	0.183	0.277	3.522	1.070	1.621
		012	Recovery-Recovery Euthanasia 1	362.80	9.132	2.517	4.390	0.647	0.178	0.311	3.802	1.048	1.828
		013	Recovery-Recovery Euthanasia 1	304.00	7.466	2.456	3.559	0.542	0.178	0.258	3.191	1.050	1.521
		014	Recovery-Recovery Euthanasia 1	283.80	7.437	2.621	3.624	0.655	0.231	0.319	3.421	1.205	1.667
		015	Recovery-Recovery Euthanasia 1	379.20	10.744	2.833	5.037	0.597	0.157	0.280	3.800	1.002	1.782

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Liver			Spleen			Testis		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
2	30 µg/day	016	Dosing-Terminal Euthanasia	257.4	7.531	2.926	4.267	0.790	0.307	0.448	3.506	1.362	1.986
		017	Dosing-Terminal Euthanasia	284.4	7.900	2.778	4.053	0.782	0.275	0.401	3.547	1.247	1.820
		018	Dosing-Terminal Euthanasia	267.3	8.757	3.276	4.762	0.775	0.290	0.421	3.004	1.124	1.633
		019	Dosing-Terminal Euthanasia	289.1	8.317	2.877	4.694	0.626	0.217	0.353	3.508	1.213	1.980
		020	Dosing-Terminal Euthanasia	250.2	7.481	2.990	3.729	0.747	0.299	0.372	3.406	1.361	1.698
		021	Dosing-Terminal Euthanasia	269.6	7.714	2.861	3.741	0.933	0.346	0.452	3.582	1.329	1.737
		022	Dosing-Terminal Euthanasia	268.5	7.203	2.683	4.125	0.697	0.260	0.399	3.037	1.131	1.739
		023	Dosing-Terminal Euthanasia	274.5	7.457	2.717	4.075	0.767	0.279	0.419	3.480	1.268	1.902
		024	Dosing-Terminal Euthanasia	248.5	7.389	2.973	3.635	0.646	0.260	0.318	3.480	1.400	1.712
		025	Dosing-Terminal Euthanasia	302.2	8.131	2.691	3.770	0.937	0.310	0.434	4.133	1.368	1.916
		026	Recovery-Recovery Euthanasia 1	351.50	9.462	2.692	5.213	0.674	0.192	0.371	3.169	0.902	1.746
		027	Recovery-Recovery Euthanasia 1	340.00	8.740	2.571	4.807	0.710	0.209	0.391	2.955	0.869	1.625
		028	Recovery-Recovery Euthanasia 1	335.40	8.136	2.426	3.912	0.703	0.210	0.338	3.595	1.072	1.728
		029	Recovery-Recovery Euthanasia 1	350.40	9.145	2.610	4.435	0.727	0.207	0.353	3.828	1.092	1.856
		030	Recovery-Recovery Euthanasia 1	380.20	9.353	2.460	4.630	0.801	0.211	0.397	3.744	0.985	1.853

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Liver			Spleen			Testis		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
3	30 µg /day	031	Dosing-Terminal Euthanasia	244.7	7.476	3.055	4.135	0.850	0.347	0.470	3.361	1.374	1.859
		032	Dosing-Terminal Euthanasia	254.6	7.377	2.897	3.889	0.775	0.304	0.409	3.475	1.365	1.832
		033	Dosing-Terminal Euthanasia	301.1	8.757	2.908	4.502	0.838	0.278	0.431	2.980	0.990	1.532
		034	Dosing-Terminal Euthanasia	250.4	6.773	2.705	3.677	0.680	0.272	0.369	2.942	1.175	1.597
		035	Dosing-Terminal Euthanasia	235.8	7.037	2.984	3.661	0.799	0.339	0.416	3.422	1.451	1.780
		036	Dosing-Terminal Euthanasia	278.8	7.802	2.798	4.111	0.736	0.264	0.388	3.126	1.121	1.647
		037	Dosing-Terminal Euthanasia	273.2	8.310	3.042	4.465	0.976	0.357	0.524	3.090	1.131	1.660
		038	Dosing-Terminal Euthanasia	258.7	7.656	2.959	3.924	0.883	0.341	0.453	3.263	1.261	1.672
		039	Dosing-Terminal Euthanasia	262.2	7.155	2.729	3.675	0.730	0.278	0.375	3.445	1.314	1.769
		040	Dosing-Terminal Euthanasia	266.4	7.529	2.826	3.744	0.717	0.269	0.357	3.612	1.356	1.796
		041	Recovery-Recovery Euthanasia 1	339.00	8.953	2.641	4.658	0.478	0.141	0.249	3.415	1.007	1.777
		042	Recovery-Recovery Euthanasia 1	325.50	8.199	2.519	4.179	0.671	0.206	0.342	4.027	1.237	2.052
		043	Recovery-Recovery Euthanasia 1	344.20	8.854	2.572	4.566	0.624	0.181	0.322	3.508	1.019	1.809
		044	Recovery-Recovery Euthanasia 1	347.50	9.468	2.725	4.885	0.782	0.225	0.404	3.825	1.101	1.974
		045	Recovery-Recovery Euthanasia 1	315.60	8.320	2.636	4.282	0.747	0.237	0.384	3.694	1.170	1.901

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

					Thymus		
Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	ABS	OW:BW	OW:BRN
1	0 µg/day	001	Dosing-Terminal Euthanasia	269.7	0.581	0.215	0.317
		002	Dosing-Terminal Euthanasia	321.3	0.611	0.190	0.316
		003	Dosing-Terminal Euthanasia	300.0	0.643	0.214	0.330
		004	Dosing-Terminal Euthanasia	315.7	0.681	0.216	0.325
		005	Dosing-Terminal Euthanasia	294.1	0.522	0.177	0.271
		006	Dosing-Terminal Euthanasia	304.8	0.556	0.182	0.300
		007	Dosing-Terminal Euthanasia	304.1	0.657	0.216	0.347
		008	Dosing-Terminal Euthanasia	286.7	0.484	0.169	0.275
		009	Dosing-Terminal Euthanasia	276.4	0.653	0.236	0.336
		010	Dosing-Terminal Euthanasia	287.8	0.526	0.183	0.282
		011	Recovery-Recovery Euthanasia 1	329.10	0.397	0.121	0.183
		012	Recovery-Recovery Euthanasia 1	362.80	0.407	0.112	0.196
		013	Recovery-Recovery Euthanasia 1	304.00	0.519	0.171	0.247
		014	Recovery-Recovery Euthanasia 1	283.80	0.583	0.205	0.284
		015	Recovery-Recovery Euthanasia 1	379.20	0.563	0.148	0.264

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

					Thymus		
Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	ABS	OW:BW	OW:BRN
2	30 µg/day	016	Dosing-Terminal Euthanasia	257.4	0.351	0.136	0.199
		017	Dosing-Terminal Euthanasia	284.4	0.650	0.229	0.334
		018	Dosing-Terminal Euthanasia	267.3	0.466	0.174	0.253
		019	Dosing-Terminal Euthanasia	289.1	0.412	0.143	0.233
		020	Dosing-Terminal Euthanasia	250.2	0.409	0.163	0.204
		021	Dosing-Terminal Euthanasia	269.6	0.479	0.178	0.232
		022	Dosing-Terminal Euthanasia	268.5	0.562	0.209	0.322
		023	Dosing-Terminal Euthanasia	274.5	0.469	0.171	0.256
		024	Dosing-Terminal Euthanasia	248.5	0.353	0.142	0.174
		025	Dosing-Terminal Euthanasia	302.2	0.522	0.173	0.242
		026	Recovery-Recovery Euthanasia 1	351.50	0.572	0.163	0.315
		027	Recovery-Recovery Euthanasia 1	340.00	0.492	0.145	0.271
		028	Recovery-Recovery Euthanasia 1	335.40	0.530	0.158	0.255
		029	Recovery-Recovery Euthanasia 1	350.40	0.525	0.150	0.255
		030	Recovery-Recovery Euthanasia 1	380.20	0.649	0.171	0.321

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Male

					Thymus		
Group Number	**Dose**	**Animal Number**	**Phase-Planned Sacrifice Group**	**BW (g)**	**ABS**	**OW:BW**	**OW:BRN**
3	30 µg /day	031	Dosing-Terminal Euthanasia	244.7	0.306	0.125	0.169
		032	Dosing-Terminal Euthanasia	254.6	0.550	0.216	0.290
		033	Dosing-Terminal Euthanasia	301.1	0.573	0.190	0.295
		034	Dosing-Terminal Euthanasia	250.4	0.332	0.133	0.180
		035	Dosing-Terminal Euthanasia	235.8	0.343	0.145	0.178
		036	Dosing-Terminal Euthanasia	278.8	0.460	0.165	0.242
		037	Dosing-Terminal Euthanasia	273.2	0.454	0.166	0.244
		038	Dosing-Terminal Euthanasia	258.7	0.359	0.139	0.184
		039	Dosing-Terminal Euthanasia	262.2	0.396	0.151	0.203
		040	Dosing-Terminal Euthanasia	266.4	0.427	0.160	0.212
		041	Recovery-Recovery Euthanasia 1	339.00	0.348	0.103	0.181
		042	Recovery-Recovery Euthanasia 1	325.50	0.525	0.161	0.268
		043	Recovery-Recovery Euthanasia 1	344.20	0.366	0.106	0.189
		044	Recovery-Recovery Euthanasia 1	347.50	0.416	0.120	0.215
		045	Recovery-Recovery Euthanasia 1	315.60	0.480	0.152	0.247

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Brain			Gland, Adrenal			Heart		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
1	0 µg/day	046	Dosing-Terminal Euthanasia	185.6	1.734	0.934	1.000	0.067	0.036	0.039	0.670	0.361	0.386
		047	Dosing-Terminal Euthanasia	213.7	1.948	0.912	1.000	0.086	0.040	0.044	0.807	0.378	0.414
		048	Dosing-Terminal Euthanasia	183.1	1.928	1.053	1.000	0.075	0.041	0.039	0.757	0.413	0.393
		049	Dosing-Terminal Euthanasia	192.4	1.836	0.954	1.000	0.067	0.035	0.036	0.659	0.343	0.359
		050	Dosing-Terminal Euthanasia	206.6	1.913	0.926	1.000	0.107	0.052	0.056	0.640	0.310	0.335
		051	Dosing-Terminal Euthanasia	207.2	1.837	0.887	1.000	0.100	0.048	0.054	0.865	0.417	0.471
		052	Dosing-Terminal Euthanasia	201.7	1.905	0.944	1.000	0.094	0.047	0.049	0.738	0.366	0.387
		053	Dosing-Terminal Euthanasia	202.0	1.907	0.944	1.000	0.080	0.040	0.042	0.833	0.412	0.437
		054	Dosing-Terminal Euthanasia	207.8	1.797	0.865	1.000	0.114	0.055	0.063	0.803	0.386	0.447
		055	Dosing-Terminal Euthanasia	187.2	1.805	0.964	1.000	0.092	0.049	0.051	0.678	0.362	0.376
		056	Recovery-Recovery Euthanasia 1	230.00	1.854	0.806	1.000	0.093	0.040	0.050	0.759	0.330	0.409
		057	Recovery-Recovery Euthanasia 1	202.70	1.804	0.890	1.000	0.077	0.038	0.043	0.689	0.340	0.382
		058	Recovery-Recovery Euthanasia 1	203.30	1.668	0.820	1.000	0.084	0.041	0.050	0.702	0.345	0.421
		059	Recovery-Recovery Euthanasia 1	200.80	1.938	0.965	1.000	0.100	0.050	0.052	0.691	0.344	0.357
		060	Recovery-Recovery Euthanasia 1	231.40	1.904	0.823	1.000	0.079	0.034	0.041	0.815	0.352	0.428

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Brain			Gland, Adrenal			Heart		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
2	30 µg/day	061	Dosing-Terminal Euthanasia	201.9	1.753	0.868	1.000	0.091	0.045	0.052	0.842	0.417	0.480
		062	Dosing-Terminal Euthanasia	188.0	1.846	0.982	1.000	0.076	0.040	0.041	0.733	0.390	0.397
		063	Dosing-Terminal Euthanasia	180.5	1.678	0.930	1.000	0.082	0.045	0.049	0.875	0.485	0.521
		064	Dosing-Terminal Euthanasia	197.0	1.834	0.931	1.000	0.096	0.049	0.052	0.699	0.355	0.381
		065	Dosing-Terminal Euthanasia	196.8	1.808	0.919	1.000	0.073	0.037	0.040	0.733	0.372	0.405
		066	Dosing-Terminal Euthanasia	194.9	1.844	0.946	1.000	0.076	0.039	0.041	0.669	0.343	0.363
		067	Dosing-Terminal Euthanasia	198.0	1.845	0.932	1.000	0.113	0.057	0.061	0.775	0.391	0.420
		068	Dosing-Terminal Euthanasia	175.3	1.713	0.977	1.000	0.069	0.039	0.040	0.607	0.346	0.354
		069	Dosing-Terminal Euthanasia	211.6	1.762	0.833	1.000	0.108	0.051	0.061	0.861	0.407	0.489
		070	Dosing-Terminal Euthanasia	201.6	1.785	0.885	1.000	0.102	0.051	0.057	0.779	0.386	0.436
		071	Recovery-Recovery Euthanasia 1	216.00	2.093	0.969	1.000	0.088	0.041	0.042	0.778	0.360	0.372
		072	Recovery-Recovery Euthanasia 1	216.00	1.759	0.814	1.000	0.070	0.032	0.040	0.939	0.435	0.534
		073	Recovery-Recovery Euthanasia 1	205.20	1.900	0.926	1.000	0.087	0.042	0.046	0.690	0.336	0.363
		074	Recovery-Recovery Euthanasia 1	209.20	1.850	0.884	1.000	0.104	0.050	0.056	0.890	0.425	0.481
		075	Recovery-Recovery Euthanasia 1	220.40	1.764	0.800	1.000	0.103	0.047	0.058	1.032	0.468	0.585

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Brain			Gland, Adrenal			Heart		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
3	30 µg /day	076	Dosing-Terminal Euthanasia	192.2	1.758	0.915	1.000	0.024e	0.012e	0.014e	0.686	0.357	0.390
		077	Dosing-Terminal Euthanasia	190.0	1.757	0.925	1.000	0.074	0.039	0.042	0.748	0.394	0.426
		078	Dosing-Terminal Euthanasia	201.5	1.899	0.942	1.000	0.094	0.047	0.049	0.843	0.418	0.444
		079	Dosing-Terminal Euthanasia	200.8	1.806	0.899	1.000	0.095	0.047	0.053	0.720	0.359	0.399
		080	Dosing-Terminal Euthanasia	199.4	1.896	0.951	1.000	0.113	0.057	0.060	0.707	0.355	0.373
		081	Dosing-Terminal Euthanasia	185.4	1.868	1.008	1.000	0.069	0.037	0.037	0.615	0.332	0.329
		082	Dosing-Terminal Euthanasia	184.3	1.842	0.999	1.000	0.072	0.039	0.039	0.640	0.347	0.347
		083	Dosing-Terminal Euthanasia	192.1	1.822	0.948	1.000	0.124	0.065	0.068	0.881	0.459	0.484
		084	Dosing-Terminal Euthanasia	191.9	2.001	1.043	1.000	0.097	0.051	0.048	0.678	0.353	0.339
		085	Dosing-Terminal Euthanasia	180.6	1.758	0.973	1.000	0.078	0.043	0.044	0.655	0.363	0.373
		086	Recovery-Recovery Euthanasia 1	210.30	1.785	0.849	1.000	0.099	0.047	0.055	0.719	0.342	0.403
		087	Recovery-Recovery Euthanasia 1	237.80	1.819	0.765	1.000	0.092	0.039	0.051	0.930	0.391	0.511
		088	Recovery-Recovery Euthanasia 1	182.40	1.918	1.052	1.000	0.089	0.049	0.046	0.760	0.417	0.396
		089	Recovery-Recovery Euthanasia 1	212.50	1.862	0.876	1.000	0.079	0.037	0.042	0.776	0.365	0.417
		090	Recovery-Recovery Euthanasia 1	208.80	1.841	0.882	1.000	0.091	0.044	0.049	0.920	0.441	0.500

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Kidney			Liver			Ovary		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
1	0 µg/day	046	Dosing-Terminal Euthanasia	185.6	1.528	0.823	0.881	5.132	2.765	2.960	0.105	0.057	0.061
		047	Dosing-Terminal Euthanasia	213.7	1.491	0.698	0.765	6.077	2.844	3.120	0.126	0.059	0.065
		048	Dosing-Terminal Euthanasia	183.1	1.521	0.831	0.789	4.935	2.695	2.560	0.124	0.068	0.064
		049	Dosing-Terminal Euthanasia	192.4	1.416	0.736	0.771	5.284	2.746	2.878	0.103	0.054	0.056
		050	Dosing-Terminal Euthanasia	206.6	1.638	0.793	0.856	5.809	2.812	3.037	0.129	0.062	0.067
		051	Dosing-Terminal Euthanasia	207.2	1.545	0.746	0.841	5.489	2.649	2.988	0.085	0.041	0.046
		052	Dosing-Terminal Euthanasia	201.7	1.563	0.775	0.820	5.626	2.789	2.953	0.118	0.059	0.062
		053	Dosing-Terminal Euthanasia	202.0	1.514	0.750	0.794	5.556	2.750	2.913	0.130	0.064	0.068
		054	Dosing-Terminal Euthanasia	207.8	1.653	0.795	0.920	5.314	2.557	2.957	0.137	0.066	0.076
		055	Dosing-Terminal Euthanasia	187.2	1.404	0.750	0.778	5.349	2.857	2.963	0.110	0.059	0.061
		056	Recovery-Recovery Euthanasia 1	230.00	1.694	0.737	0.914	6.030	2.622	3.252	0.149	0.065	0.080
		057	Recovery-Recovery Euthanasia 1	202.70	1.340	0.661	0.743	5.280	2.605	2.927	0.090	0.044	0.050
		058	Recovery-Recovery Euthanasia 1	203.30	1.392	0.685	0.835	5.299	2.606	3.177	0.097	0.048	0.058
		059	Recovery-Recovery Euthanasia 1	200.80	1.560	0.777	0.805	5.176	2.578	2.671	0.114	0.057	0.059
		060	Recovery-Recovery Euthanasia 1	231.40	1.660	0.717	0.872	6.028	2.605	3.166	0.171	0.074	0.090

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Kidney			Liver			Ovary		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
2	30 µg/day	061	Dosing-Terminal Euthanasia	201.9	1.579	0.782	0.901	6.265	3.103	3.574	0.121	0.060	0.069
		062	Dosing-Terminal Euthanasia	188.0	1.595	0.848	0.864	5.849	3.111	3.168	0.071	0.038	0.038
		063	Dosing-Terminal Euthanasia	180.5	1.550	0.859	0.924	4.987	2.763	2.972	0.087	0.048	0.052
		064	Dosing-Terminal Euthanasia	197.0	1.528	0.776	0.833	5.364	2.723	2.925	0.106	0.054	0.058
		065	Dosing-Terminal Euthanasia	196.8	1.621	0.824	0.897	6.048	3.073	3.345	0.120	0.061	0.066
		066	Dosing-Terminal Euthanasia	194.9	1.662	0.853	0.901	5.055	2.594	2.741	0.115	0.059	0.062
		067	Dosing-Terminal Euthanasia	198.0	1.720	0.869	0.932	5.548	2.802	3.007	0.124	0.063	0.067
		068	Dosing-Terminal Euthanasia	175.3	1.614	0.921	0.942	4.941	2.819	2.884	0.121	0.069	0.071
		069	Dosing-Terminal Euthanasia	211.6	1.766	0.835	1.002	6.512	3.078	3.696	0.095	0.045	0.054
		070	Dosing-Terminal Euthanasia	201.6	1.708	0.847	0.957	5.921	2.937	3.317	0.093	0.046	0.052
		071	Recovery-Recovery Euthanasia 1	216.00	1.620	0.750	0.774	5.605	2.595	2.678	0.125	0.058	0.060
		072	Recovery-Recovery Euthanasia 1	216.00	1.591	0.737	0.904	6.056	2.804	3.443	0.078	0.036	0.044
		073	Recovery-Recovery Euthanasia 1	205.20	1.482	0.722	0.780	5.460	2.661	2.874	0.170	0.083	0.089
		074	Recovery-Recovery Euthanasia 1	209.20	1.723	0.824	0.931	5.655	2.703	3.057	0.166	0.079	0.090
		075	Recovery-Recovery Euthanasia 1	220.40	1.828	0.829	1.036	6.258	2.839	3.548	0.113	0.051	0.064

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Kidney			Liver			Ovary		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
3	30 µg /day	076	Dosing-Terminal Euthanasia	192.2	1.596	0.830	0.908	5.669	2.950	3.225	0.015e	0.008e	0.009e
		077	Dosing-Terminal Euthanasia	190.0	1.529	0.805	0.870	5.637	2.967	3.208	0.092	0.048	0.052
		078	Dosing-Terminal Euthanasia	201.5	1.750	0.868	0.922	6.241	3.097	3.286	0.116	0.058	0.061
		079	Dosing-Terminal Euthanasia	200.8	1.794	0.893	0.993	6.541	3.257	3.622	0.127	0.063	0.070
		080	Dosing-Terminal Euthanasia	199.4	1.684	0.845	0.888	6.451	3.235	3.402	0.139	0.070	0.073
		081	Dosing-Terminal Euthanasia	185.4	1.669	0.900	0.893	5.539	2.988	2.965	0.116	0.063	0.062
		082	Dosing-Terminal Euthanasia	184.3	1.402	0.761	0.761	5.071	2.751	2.753	0.096	0.052	0.052
		083	Dosing-Terminal Euthanasia	192.1	1.756	0.914	0.964	5.806	3.022	3.187	0.119	0.062	0.065
		084	Dosing-Terminal Euthanasia	191.9	1.590	0.829	0.795	5.941	3.096	2.969	0.110	0.057	0.055
		085	Dosing-Terminal Euthanasia	180.6	1.394	0.772	0.793	5.208	2.884	2.962	0.087	0.048	0.049
		086	Recovery-Recovery Euthanasia 1	210.30	1.615	0.768	0.905	5.322	2.531	2.982	0.147	0.070	0.082
		087	Recovery-Recovery Euthanasia 1	237.80	1.823	0.767	1.002	6.706	2.820	3.687	0.169	0.071	0.093
		088	Recovery-Recovery Euthanasia 1	182.40	1.725	0.946	0.899	5.371	2.945	2.800	0.119	0.065	0.062
		089	Recovery-Recovery Euthanasia 1	212.50	1.737	0.817	0.933	5.787	2.723	3.108	0.112	0.053	0.060
		090	Recovery-Recovery Euthanasia 1	208.80	1.670	0.800	0.907	5.952	2.851	3.233	0.112	0.054	0.061

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Spleen			Thymus		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
1	0 µg/day	046	Dosing-Terminal Euthanasia	185.6	0.356	0.192	0.205	0.457	0.246	0.264
		047	Dosing-Terminal Euthanasia	213.7	0.501	0.234	0.257	0.426	0.199	0.219
		048	Dosing-Terminal Euthanasia	183.1	0.348	0.190	0.180	0.373	0.204	0.193
		049	Dosing-Terminal Euthanasia	192.4	0.516	0.268	0.281	0.538	0.280	0.293
		050	Dosing-Terminal Euthanasia	206.6	0.490	0.237	0.256	0.573	0.277	0.300
		051	Dosing-Terminal Euthanasia	207.2	0.416	0.201	0.226	0.413	0.199	0.225
		052	Dosing-Terminal Euthanasia	201.7	0.532	0.264	0.279	0.527	0.261	0.277
		053	Dosing-Terminal Euthanasia	202.0	0.389	0.193	0.204	0.396	0.196	0.208
		054	Dosing-Terminal Euthanasia	207.8	0.425	0.205	0.237	0.493	0.237	0.274
		055	Dosing-Terminal Euthanasia	187.2	0.409	0.218	0.227	0.392	0.209	0.217
		056	Recovery-Recovery Euthanasia 1	230.00	0.565	0.246	0.305	0.410	0.178	0.221
		057	Recovery-Recovery Euthanasia 1	202.70	0.413	0.204	0.229	0.392	0.193	0.217
		058	Recovery-Recovery Euthanasia 1	203.30	0.332	0.163	0.199	0.496	0.244	0.297
		059	Recovery-Recovery Euthanasia 1	200.80	0.380	0.189	0.196	0.336	0.167	0.173
		060	Recovery-Recovery Euthanasia 1	231.40	0.516	0.223	0.271	0.505	0.218	0.265

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Spleen			Thymus		
					ABS	OW:BW	OW:BRN	ABS	OW:BW	OW:BRN
2	30 µg/day	061	Dosing-Terminal Euthanasia	201.9	0.712	0.353	0.406	0.447	0.221	0.255
		062	Dosing-Terminal Euthanasia	188.0	0.694	0.369	0.376	0.380	0.202	0.206
		063	Dosing-Terminal Euthanasia	180.5	0.640	0.355	0.381	0.530	0.294	0.316
		064	Dosing-Terminal Euthanasia	197.0	0.884	0.449	0.482	0.372	0.189	0.203
		065	Dosing-Terminal Euthanasia	196.8	0.785	0.399	0.434	0.400	0.203	0.221
		066	Dosing-Terminal Euthanasia	194.9	0.552	0.283	0.299	0.495	0.254	0.268
		067	Dosing-Terminal Euthanasia	198.0	0.598	0.302	0.324	0.387	0.195	0.210
		068	Dosing-Terminal Euthanasia	175.3	0.552	0.315	0.322	0.121	0.069	0.071
		069	Dosing-Terminal Euthanasia	211.6	0.674	0.319	0.383	0.478	0.226	0.271
		070	Dosing-Terminal Euthanasia	201.6	0.705	0.350	0.395	0.357	0.177	0.200
		071	Recovery-Recovery Euthanasia 1	216.00	0.476	0.220	0.227	0.429	0.199	0.205
		072	Recovery-Recovery Euthanasia 1	216.00	0.411	0.190	0.234	0.463	0.214	0.263
		073	Recovery-Recovery Euthanasia 1	205.20	0.482	0.235	0.254	0.406	0.198	0.214
		074	Recovery-Recovery Euthanasia 1	209.20	0.504	0.241	0.272	0.460	0.220	0.249
		075	Recovery-Recovery Euthanasia 1	220.40	0.500	0.227	0.283	0.431	0.196	0.244

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Appendix 10

Organ Weights (g) and Ratios

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Female

Group Number	Dose	Animal Number	Phase-Planned Sacrifice Group	BW (g)	Spleen ABS	Spleen OW:BW	Spleen OW:BRN	Thymus ABS	Thymus OW:BW	Thymus OW:BRN
3	30 µg /day	076	Dosing-Terminal Euthanasia	192.2	0.601	0.313	0.342	0.339	0.176	0.193
		077	Dosing-Terminal Euthanasia	190.0	0.583	0.307	0.332	0.399	0.210	0.227
		078	Dosing-Terminal Euthanasia	201.5	0.610	0.303	0.321	0.374	0.186	0.197
		079	Dosing-Terminal Euthanasia	200.8	0.712	0.355	0.394	0.410	0.204	0.227
		080	Dosing-Terminal Euthanasia	199.4	0.635	0.318	0.335	0.518	0.260	0.273
		081	Dosing-Terminal Euthanasia	185.4	0.543	0.293	0.291	0.419	0.226	0.224
		082	Dosing-Terminal Euthanasia	184.3	0.677	0.367	0.368	0.363	0.197	0.197
		083	Dosing-Terminal Euthanasia	192.1	0.684	0.356	0.375	0.402	0.209	0.221
		084	Dosing-Terminal Euthanasia	191.9	0.587	0.306	0.293	0.295	0.154	0.147
		085	Dosing-Terminal Euthanasia	180.6	0.567	0.314	0.323	0.387	0.214	0.220
		086	Recovery-Recovery Euthanasia 1	210.30	0.378	0.180	0.212	0.413	0.196	0.231
		087	Recovery-Recovery Euthanasia 1	237.80	0.532	0.224	0.292	0.425	0.179	0.234
		088	Recovery-Recovery Euthanasia 1	182.40	0.347	0.190	0.181	0.317	0.174	0.165
		089	Recovery-Recovery Euthanasia 1	212.50	0.461	0.217	0.248	0.418	0.197	0.224
		090	Recovery-Recovery Euthanasia 1	208.80	0.518	0.248	0.281	0.388	0.186	0.211

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Footnotes

NOS = Not otherwise specified.

Note: All tissues are considered as macroscopically unremarkable unless noted in the individual animal listings.

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
001	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Site, Injection	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach
Testis	Thymus	Tongue	Trachea	Ureter
Urinary Bladder				

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
002	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Gland, Thyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Lymph Node, Inguinal	No macroscopic observations on tissue		Missing

The following required protocol tissues were not examined microscopically:

Lymph Node, Inguinal

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Draining	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Pancreas	Site, Injection	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
003	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Kidney	No macroscopic observations on tissue		Dilatation, Pelvis, Unilateral, Minimal
Lung			Tissue is unremarkable
	Abnormal color, Dark, Focal, 0.3-0.5 cm, Left lobe	Not Correlated	
Lymph Node, Inguinal			Tissue is unremarkable
	Abnormal size, Enlarged, Right	Not Correlated	
Nerve, Optic			Tissue Comment: examined along with the eye sections
	No macroscopic observations on tissue		
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
003	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lymph Node, Draining	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen
Stomach	Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder			

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
004	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
005	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
006	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Site, Injection	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Spleen	Stomach	Testis	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
007	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Pancreas	Site, Injection	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
008	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
009	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Epididymis
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary
Gland, Seminal Vesicle	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Site, Injection	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach
Testis	Thymus	Tongue	Trachea	Ureter
Urinary Bladder				

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
010	M	1	0 µg/day	17	Dosing	Terminal Euthanasia

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain
Epididymis	Esophagus	Eye	Gland, Adrenal
Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Liver
Lung	Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Site, Injection	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach
Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder		

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
011	M	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Missing
Adipose Tissue	Abnormal color, Dark, Focal /Comments: Abdominal	Correlated	Inflammation, Mild
	Abnormal consistency, Firm, Focal	Correlated	Fibrosis, Minimal
	Abnormal consistency, Firm, Focal	Correlated	Inflammation, Mild

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Site, Injection

Spleen

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
012	M	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Draining Site, Injection

Spleen

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
013	M	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Draining Site, Injection
Spleen

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
014	M	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum	Joint	Liver	Lymph Node, Draining
Lymph Node, Inguinal	Site, Injection	Spleen	

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
015	M	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum	Joint	Liver	Lymph Node, Draining
Lymph Node, Inguinal	Site, Injection	Spleen	

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
016	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
016	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Testis	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
017	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Liver			Vacuolation, Hepatocyte; Periportal, Minimal
	Abnormal surface, Raised, Focal, < 0.3 cm	Not Correlated	
Lung			Tissue is unremarkable
	Abnormal color, Pale, Focal, Right caudal lobe	Not Correlated	
Lymph Node, Draining	Abnormal size, Enlarged, Left	Correlated	Increased cellularity, Germinal center, Mild
	Abnormal size, Enlarged, Left	Correlated	Increased cellularity, Plasma cell, Mild
Site, Injection	Abnormal color, Dark, Focal, 0.3-0.5 cm	Correlated	Edema, Mild
	Abnormal color, Dark, Focal, 0.3-0.5 cm	Correlated	Inflammation, Moderate
	Abnormal consistency, Firm, Focal	Correlated	Edema, Mild
	Abnormal consistency, Firm, Focal	Correlated	Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
			Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
017	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Testis	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
018	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Pituitary	No macroscopic observations on tissue		Cyst, Pars anterior (distalis), Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Moderate
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
018	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Inguinal	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach
Testis	Thymus	Tongue	Trachea	Ureter
Urinary Bladder				

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
019	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Kidney	No macroscopic observations on tissue		Tubular basophilia, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
019	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
020	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	Abnormal consistency, Firm, Focal, Site, Injection, 9 Abnormal consistency, Firm, Focal, Site, Injection, 9	Correlated Correlated	Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
020	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
021	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Mammary	No macroscopic observations on tissue		Missing
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Missing
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Moderate Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		Both Missing

The following required protocol tissues were not examined microscopically:

Gland, Mammary Lymph Node, Draining Ureter

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
021	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Parathyroid
Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Testis	Thymus
Tongue	Trachea	Urinary Bladder		

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
022	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Site, Injection	Abnormal color, Pale, Diffuse Abnormal color, Pale, Diffuse	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
022	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord
Stomach	Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
023	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	No macroscopic observations on tissue		Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
023	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Draining
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord
Stomach	Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
024	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
024	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord
Stomach	Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
025	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Moderate
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
025	M	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Lung	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
026	M	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	Abnormal size, Enlarged	Correlated	Increased cellularity, Germinal center, Minimal
	Abnormal size, Enlarged	Correlated	Increased cellularity, Plasma cell, Minimal
	Abnormal size, Enlarged	Correlated	Infiltration, Macrophage, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
027	M	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
028	M	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
029	M	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
030	M	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
031	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Pituitary	No macroscopic observations on tissue		Cyst, Pars anterior (distalis), Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Moderate Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
031	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Lung	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
032	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
032	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord
Stomach	Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder			

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
033	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Moderate
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
033	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
034	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
034	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
035	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Gland, Pituitary	No macroscopic observations on tissue		Cyst, Pars anterior (distalis), Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal
Stomach	No macroscopic observations on tissue		Erosion, Nonglandular mucosa, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
035	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Testis	Thymus	Tongue
Trachea	Ureter	Urinary Bladder		

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
036	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Prostate	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
036	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Seminal Vesicle	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
037	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Kidney	No macroscopic observations on tissue		Infiltration mononuclear cell, Unilateral, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
037	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Large Intestine, Cecum
Large Intestine, Colon	Lung	Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach
Testis	Thymus	Tongue	Trachea	Ureter
Urinary Bladder				

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
038	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
038	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
039	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	Abnormal consistency, Firm, Focal, Site, Injection, 9 Abnormal consistency, Firm, Focal, Site, Injection, 9	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
039	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Testis
Thymus	Tongue	Trachea	Ureter	Urinary Bladder

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
040	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Mild
Site, Injection	Abnormal color, Pale, Diffuse Abnormal color, Pale, Diffuse	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
040	M	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Epididymis	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Prostate	Gland, Salivary	Gland, Seminal Vesicle
Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Pancreas
Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord
Stomach	Testis	Thymus	Tongue	Trachea
Ureter	Urinary Bladder			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
041	M	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
042	M	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
043	M	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Mild
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
044	M	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Infiltration, Macrophage, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
045	M	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
046	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Adrenal	No macroscopic observations on tissue		Tissue Comment: medulla missing unilaterally
Site, Injection	Abnormal color, Dark, Focal, < 0.3 cm, Site, Injection, 9	Correlated	Inflammation, Minimal
Urinary Bladder	No macroscopic observations on tissue		Missing

The following required protocol tissues were not examined microscopically:

Urinary Bladder

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Draining	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Thymus
Tongue	Trachea	Ureter	Uterus	Vagina

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
047	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Draining	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
048	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Eye	No macroscopic observations on tissue		Rosettes retina, Minimal
Gland, Harderian	No macroscopic observations on tissue		Degeneration/Necrosis, Minimal Infiltration mononuclear cell, Minimal
Kidney	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Joint	Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung
Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Site, Injection	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen
Stomach	Thymus	Tongue	Trachea	Ureter
Urinary Bladder	Uterus	Vagina		

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
049	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Harderian	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Gland, Pituitary	No macroscopic observations on tissue		Cyst, Minimal
Gland, Salivary	No macroscopic observations on tissue		Hypertrophy, Minimal
Gut-Associated Lymphoid Tissue	No macroscopic observations on tissue		Missing

The following required protocol tissues were not examined microscopically:

Gut-Associated Lymphoid Tissue

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Thyroid	Heart	Joint	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Draining
Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Site, Injection	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen
Stomach	Thymus	Tongue	Trachea	Ureter
Urinary Bladder	Uterus	Vagina		

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
050	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Adrenal	No macroscopic observations on tissue		Tissue Comment: Adrenal medulla missing unilaterally
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Gland, Pituitary	No macroscopic observations on tissue		Tissue Comment: Pars distalis only
Gut-Associated Lymphoid Tissue	No macroscopic observations on tissue		Missing
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

Gut-Associated
Lymphoid Tissue

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
050	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Liver	Lung	Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Spleen	Stomach	Thymus	Tongue
Trachea	Ureter	Urinary Bladder	Uterus	Vagina

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
051	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Adrenal	No macroscopic observations on tissue		Tissue Comment: Adrenal medulla missing unilaterally
Gland, Harderian	No macroscopic observations on tissue		Degeneration/Necrosis, Minimal
Kidney	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
051	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Large Intestine, Cecum	Large Intestine, Colon	Liver
Lung	Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct	Pancreas
Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord
Spleen	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
052	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Draining	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Pancreas	Site, Injection	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach
Thymus	Tongue	Trachea	Ureter	Urinary Bladder
Uterus	Vagina			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
053	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Joint	No macroscopic observations on tissue		Physeal dysplasia, Focal, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Liver	Lung	Lymph Node, Draining	Lymph Node, Inguinal	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Site, Injection	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
054	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Pituitary	No macroscopic observations on tissue		Tissue Comment: Pars distalis only

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital
Gland, Mammary	Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid
Gut-Associated Lymphoid Tissue	Heart	Joint	Kidney	Large Intestine, Cecum
Large Intestine, Colon	Liver	Lung	Lymph Node, Draining	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Pancreas	Site, Injection	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach
Thymus	Tongue	Trachea	Ureter	Urinary Bladder
Uterus	Vagina			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
055	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Gland, Harderian	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Lung	No macroscopic observations on tissue		Infiltration mixed cell, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
055	F	1	0 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone Marrow, Sternum	Bone, Sternum	Brain	Cervix
Esophagus	Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Liver	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Spleen	Stomach
Thymus	Tongue	Trachea	Ureter	Urinary Bladder
Uterus	Vagina			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
056	F	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum	Joint	Liver	Lymph Node, Draining
Lymph Node, Inguinal	Site, Injection	Spleen	

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
057	F	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Draining Site, Injection
Spleen

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
058	F	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum	Joint	Liver	Lymph Node, Draining
Lymph Node, Inguinal	Site, Injection	Spleen	

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
059	F	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum	Joint	Liver	Lymph Node, Draining
Lymph Node, Inguinal	Site, Injection	Spleen	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
060	F	1	0 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Site, Injection Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
061	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Moderate
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal
Stomach	No macroscopic observations on tissue		Infiltration mononuclear cell, Serosa, Focal, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
061	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Lung	Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Ovary	Oviduct	Pancreas	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
062	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Gland, Pituitary	No macroscopic observations on tissue		Tissue Comment: Missing, pars nervosa
Kidney	No macroscopic observations on tissue		Tubular basophilia, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Moderate
Oviduct	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Pancreas	No macroscopic observations on tissue		Atrophy, Acinar cell, Minimal Infiltration mononuclear cell, Interstitium, Focal, Minimal
Site, Injection	Abnormal consistency, Firm, Focal, Site, Injection, 9 Abnormal consistency, Firm, Focal, Site, Injection, 9	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
062	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Large Intestine, Cecum	Large Intestine, Colon	Lung
Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus	Tongue
Trachea	Ureter	Urinary Bladder	Uterus	Vagina

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
063	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Mammary	No macroscopic observations on tissue		Missing
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Moderate
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Skin	No macroscopic observations on tissue		Missing
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

Gland, Mammary Skin

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
063	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung
Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus	Tongue
Trachea	Ureter	Urinary Bladder	Uterus	Vagina

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
064	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Moderate
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Pancreas	No macroscopic observations on tissue		Atrophy, Acinar cell, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
064	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus	Tongue
Trachea	Ureter	Urinary Bladder	Uterus	Vagina

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
065	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Kidney	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Pancreas	No macroscopic observations on tissue		Atrophy, Acinar cell, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
065	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Large Intestine, Cecum	Large Intestine, Colon	Lung
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
066	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Kidney	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	Abnormal color, Pale, Diffuse	Correlated	Edema, Mild
	Abnormal color, Pale, Diffuse	Correlated	Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
066	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Large Intestine, Cecum	Large Intestine, Colon	Lung
Lymph Node, Draining	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
067	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lung	No macroscopic observations on tissue		Infiltration mixed cell, Focal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Moderate
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
067	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
068	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Moderate
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
068	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
069	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Eye	No macroscopic observations on tissue		Mineralization, Cornea, Focal, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Gut-Associated Lymphoid Tissue	No macroscopic observations on tissue		Mineralization, Germinal center, Focal, Minimal /Comments: associated with fibrosis and mixed inflammation
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Mild
Site, Injection	Abnormal color, Dark, Focal, 1-2 cm, Site, Injection, 9	Correlated	Edema, Mild
	Abnormal color, Dark, Focal, 1-2 cm, Site, Injection, 9	Correlated	Inflammation, Mild
	Abnormal consistency, Firm, Focal, Site, Injection, 9	Correlated	Edema, Mild
	Abnormal consistency, Firm, Focal, Site, Injection, 9	Correlated	Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
069	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Inguinal
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus	Tongue
Trachea	Ureter	Urinary Bladder	Uterus	Vagina

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
070	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Harderian	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Kidney	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	Abnormal size, Enlarged, Left Abnormal size, Enlarged, Left	Correlated Correlated	Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Moderate
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Pancreas	No macroscopic observations on tissue		Atrophy, Acinar cell, Minimal
Site, Injection	Abnormal color, Pale, Diffuse Abnormal color, Pale, Diffuse	Correlated Correlated	Edema, Moderate Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
070	F	2	30 µg/day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Ureter	No macroscopic observations on tissue		Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric	Muscle, Skeletal
Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach
Thymus	Tongue	Trachea	Ureter	Urinary Bladder
Uterus	Vagina			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
071	F	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Adipose Tissue	Abnormal color, Dark, Multifocal /Comments: Neck, Ventral, Yellow	Correlated	Infiltration mononuclear cell, Mild /Comments: hemosiderophages

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
072	F	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
073	F	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Spleen

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
074	F	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Joint	No macroscopic observations on tissue		Physeal dysplasia, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Mild
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Liver Lymph Node, Inguinal

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
075	F	2	30 µg/day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Infiltration, Macrophage, Mild
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal Spleen

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
076	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Eye	No macroscopic observations on tissue		Rosettes retina, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Mild
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
076	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung
Lymph Node, Inguinal	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
077	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Harderian	No macroscopic observations on tissue		Degeneration/Necrosis, Minimal
Gland, Pituitary	No macroscopic observations on tissue		Cyst, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Plasma cell, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
077	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Joint
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
078	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
078	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
079	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Lymph Node, Draining	Abnormal size, Enlarged	Correlated	Increased cellularity, Germinal center, Minimal
	Abnormal size, Enlarged	Correlated	Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	Abnormal consistency, Firm, Focal	Correlated	Edema, Mild
	Abnormal consistency, Firm, Focal	Correlated	Inflammation, Mild
Spleen	Abnormal size, Enlarged	Correlated	Increased cellularity, Germinal center, Minimal
	Abnormal size, Enlarged	Correlated	Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
079	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Liver	Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Ovary	Oviduct	Pancreas	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach
Thymus	Tongue	Trachea	Ureter	Urinary Bladder
Uterus	Vagina			

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
080	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Adrenal	No macroscopic observations on tissue		Hypertrophy, Cortex, Present
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Gland, Pituitary	No macroscopic observations on tissue		Cyst, Minimal
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Lymph Node, Draining	Abnormal size, Enlarged Abnormal size, Enlarged	Correlated Correlated	Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Moderate Inflammation, Moderate
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
080	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart	Kidney
Large Intestine, Cecum	Large Intestine, Colon	Liver	Lung	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
081	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Harderian	No macroscopic observations on tissue		Degeneration/Necrosis, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Moderate
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Site, Injection	Abnormal consistency, Firm, Focal, Site, Injection, 9 Abnormal consistency, Firm, Focal, Site, Injection, 9	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
081	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung
Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary
Oviduct	Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum
Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus	Tongue
Trachea	Ureter	Urinary Bladder	Uterus	Vagina

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
082	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Adrenal	No macroscopic observations on tissue		Tissue Comment: Medulla not in section unilaterally
Gland, Harderian	No macroscopic observations on tissue		Infiltration mononuclear cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	Abnormal size, Enlarged	Correlated	Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	Abnormal size, Enlarged, Left	Correlated	Increased cellularity, Germinal center, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
082	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
083	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Eye	No macroscopic observations on tissue		Rosettes retina, Minimal
Joint	No macroscopic observations on tissue		Inflammation, Extra-capsular, Minimal
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal
Site, Injection	No macroscopic observations on tissue		Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
083	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary	Gland, Parathyroid
Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue	Heart
Kidney	Large Intestine, Cecum	Large Intestine, Colon	Lung	Lymph Node, Mesenteric
Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral	Ovary	Oviduct
Pancreas	Skin	Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum
Spinal Cord	Stomach	Thymus	Tongue	Trachea
Ureter	Urinary Bladder	Uterus	Vagina	

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
084	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Large Intestine, Colon	No macroscopic observations on tissue		Infiltration mixed cell, Mucosa, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	Abnormal consistency, Firm, Focal Abnormal consistency, Firm, Focal	Correlated Correlated	Edema, Mild Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Hematopoietic cell, Minimal
Ureter	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
084	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Liver
Lung	Lymph Node, Draining	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic
Nerve, Peripheral	Ovary	Oviduct	Pancreas	Skin
Small Intestine, Duodenum	Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach
Thymus	Tongue	Trachea	Ureter	Urinary Bladder
Uterus	Vagina			

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
085	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Bone Marrow, Sternum	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal
Gland, Parathyroid	No macroscopic observations on tissue		One-of-pair Missing Tissue is unremarkable
Liver	No macroscopic observations on tissue		Vacuolation, Hepatocyte; Periportal, Minimal
Lymph Node, Draining	Abnormal size, Enlarged	Correlated	Increased cellularity, Germinal center, Mild
	Abnormal size, Enlarged	Correlated	Increased cellularity, Plasma cell, Mild
Lymph Node, Inguinal	Abnormal size, Enlarged, Left	Correlated	Increased cellularity, Germinal center, Mild
	Abnormal size, Enlarged, Left	Correlated	Increased cellularity, Plasma cell, Minimal
Site, Injection	Abnormal consistency, Firm, Focal	Correlated	Edema, Mild
	Abnormal consistency, Firm, Focal	Correlated	Inflammation, Mild
Spleen	No macroscopic observations on tissue		Increased cellularity, Hematopoietic cell, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

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20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
085	F	3	30 µg /day	17	Dosing	Terminal Euthanasia

The following tissues are unremarkable microscopically:

Artery, Aorta	Bone, Sternum	Brain	Cervix	Esophagus
Eye	Gland, Adrenal	Gland, Harderian	Gland, Lacrimal, Extraorbital	Gland, Mammary
Gland, Parathyroid	Gland, Pituitary	Gland, Salivary	Gland, Thyroid	Gut-Associated Lymphoid Tissue
Heart	Joint	Kidney	Large Intestine, Cecum	Large Intestine, Colon
Lung	Lymph Node, Mesenteric	Muscle, Skeletal	Nerve, Optic	Nerve, Peripheral
Ovary	Oviduct	Pancreas	Skin	Small Intestine, Duodenum
Small Intestine, Ileum	Small Intestine, Jejunum	Spinal Cord	Stomach	Thymus
Tongue	Trachea	Ureter	Urinary Bladder	Uterus
Vagina				

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
086	F	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Joint	No macroscopic observations on tissue		Physeal dysplasia, Minimal
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Liver Lymph Node, Inguinal Spleen

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Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
087	F	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Infiltration, Macrophage, Mild
Lymph Node, Inguinal	Abnormal size, Enlarged	Correlated	Increased cellularity, Germinal center, Minimal
	Abnormal size, Enlarged	Correlated	Increased cellularity, Plasma cell, Minimal
	Abnormal size, Enlarged	Correlated	Infiltration, Macrophage, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Spleen

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Document 2

Appendix 11

Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
088	F	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Mild
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Spleen

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
089	F	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	Abnormal size, Enlarged	Correlated	Increased cellularity, Germinal center, Minimal
	Abnormal size, Enlarged	Correlated	Increased cellularity, Plasma cell, Minimal
	Abnormal size, Enlarged	Correlated	Infiltration, Macrophage, Minimal
Lymph Node, Inguinal	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver

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Individual Macroscopic and Microscopic Observations w/Correlations

20GR142 : 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Animal #	Sex	Group #	Dose	Day of Death	Phase	Status
090	F	3	30 µg /day	22	Recovery	Recovery Euthanasia 1

Tissue	Macroscopic Observations / comments	Status	Microscopic Observations / comments
Lymph Node, Draining	No macroscopic observations on tissue		Increased cellularity, Germinal center, Mild Increased cellularity, Plasma cell, Minimal Infiltration, Macrophage, Mild
Site, Injection	No macroscopic observations on tissue		Inflammation, Minimal
Spleen	No macroscopic observations on tissue		Increased cellularity, Germinal center, Minimal

The following required protocol tissues were not examined microscopically:

No Tissues to list

The following tissues are unremarkable microscopically:

Bone Marrow, Sternum Joint Liver Lymph Node, Inguinal

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Dermal Assessment Left/Right Report with Individual Values

Printed: 20 Aug 2020 11:04:50 AM

Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
1	001	ER-0:...	ER-0:...	ER-0:...	-	-
	002	ER-0:...	ER-0:...	ER-0:...	-	-
	003	ER-0:...	ER-0:...	ER-0:...	-	-
	004	ER-0:...	ER-0:...	ER-0:...	-	-
	005	ER-0:...	ER-0:...	ER-0:...	-	-
	006	ER-0:...	ER-0:...	ER-0:...	-	-
	007	ER-0:...	ER-0:...	ER-0:...	-	-
	008	ER-0:...	ER-0:...	ER-0:...	-	-
	009	ER-0:...	ER-0:...	ER-0:...	-	-
	010	ER-0:...	ER-0:...	ER-0:...	-	-
	011	ER-0:...	ER-0:...	ER-0:...	-	-
	012	ER-0:...	ER-0:...	ER-0:...	-	-
	013	ER-0:...	ER-0:...	ER-0:...	-	-
	014	ER-0:...	ER-0:...	ER-0:...	-	-
	015	ER-0:...	ER-0:...	ER-0:...	-	-
2	016	ER-0:...	ER-0:...	ER-0:...	-	-
	017	ER-0:...	ER-0:...	ER-0:...	-	-
	018	ER-0:...	ER-0:...	ER-0:...	-	-
	019	ER-0:...	ER-0:...	ER-0:...	-	-
	020	ER-0:...	ER-0:...	ER-0:...	-	-
	021	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
2	022	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	023	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	024	ER-0:...	ER-0:...	ER-0:...	-	-
	025	ER-0:...	ER-0:...	ER-1:...	-	-
	026	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	027	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	028	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	029	ER-0:...	ER-0:...	ER-0:...	-	-
	030	ER-0:...	ER-0:...	ER-0:...	-	-
3	031	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	032	ER-0:...	ER-0:...	ER-0:...	-	-
	033	ER-0:...	ER-0:...	ER-0:...	-	-
	034	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	035	ER-0:...	ER-0:...	ER-0:...	-	-
	036	ER-0:...	ER-0:...	ER-0:...	-	-
	037	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	038	ER-0:...	ER-0:...	ER-0:...	-	-
	039	ER-0:...	ER-0:...	ER-0:...	-	-
	040	ER-0:...	ER-0:...	ER-0:...	-	-
	041	ER-0:...	ER-0:...	ER-1:...	-	-
	042	ER-0:...	ER-0:...	ER-0:...	-	-

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Document 2

Dermal Assessment Left/Right Report with Individual Values

Printed: 20 Aug 2020 11:04:50 AM

Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
3	043	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	044	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	045	ER-0:...	ER-0:...	ER-0:...	ER-1:...	ER-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
1	001	-	-	ER-0:...	ER-0:...	ER-0:...
	002	-	-	ER-0:...	ER-0:...	ER-0:...
	003	-	-	ER-0:...	ER-0:...	ER-0:...
	004	-	-	ER-0:...	ER-0:...	ER-0:...
	005	-	-	ER-0:...	ER-0:...	ER-0:...
	006	-	-	ER-0:...	ER-0:...	ER-0:...
	007	-	-	ER-0:...	ER-0:...	ER-0:...
	008	-	-	ER-0:...	ER-0:...	ER-0:...
	009	-	-	ER-0:...	ER-0:...	ER-0:...
	010	-	-	ER-0:...	ER-0:...	ER-0:...
	011	-	-	ER-0:...	ER-0:...	ER-0:...
	012	-	-	ER-0:...	ER-0:...	ER-0:...
	013	-	-	ER-0:...	ER-0:...	ER-0:...
	014	-	-	ER-0:...	ER-0:...	ER-0:...
	015	-	-	ER-0:...	ER-0:...	ER-0:...
2	016	-	-	ER-0:...	ER-0:...	ER-0:...
	017	-	-	ER-0:...	ER-0:...	ER-0:...
	018	-	-	ER-0:...	ER-0:...	ER-0:...
	019	-	-	ER-0:...	ER-0:...	ER-0:...
	020	-	-	ER-0:...	ER-0:...	ER-0:...
	021	-	-	ER-0:...	ER-0:...	ER-0:...

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Study: 20GR142
StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY
Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
2	022	-	-	ER-0:...	ER-0:...	ER-1:...
	023	-	-	ER-0:...	ER-0:...	ER-0:...
	024	-	-	ER-0:...	ER-0:...	ER-1:...
	025	-	-	ER-0:...	ER-0:...	ER-1:...
	026	-	-	ER-0:...	ER-0:...	ER-1:...
	027	-	-	ER-0:...	ER-0:...	ER-1:...
	028	-	-	ER-0:...	ER-0:...	ER-1:...
	029	-	-	ER-0:...	ER-0:...	ER-1:...
	030	-	-	ER-0:...	ER-0:...	ER-0:...
3	031	-	-	ER-0:...	ER-0:...	ER-1:...
	032	-	-	ER-0:...	ER-0:...	ER-1:...
	033	-	-	ER-0:...	ER-0:...	ER-1:...
	034	-	-	ER-0:...	ER-0:...	ER-1:...
	035	-	-	ER-0:...	ER-0:...	ER-1:...
	036	-	-	ER-0:...	ER-0:...	ER-1:...
	037	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-1:...
	038	-	-	ER-0:...	ER-0:...	ER-1:...
	039	-	-	ER-0:...	ER-0:...	ER-0:...
	040	-	-	ER-0:...	ER-0:...	ER-1:...
	041	-	-	ER-0:...	ER-0:...	ER-1:...
	042	-	-	ER-0:...	ER-0:...	ER-1:...

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Dermal Assessment Left/Right Report with Individual Values

Printed: 20 Aug 2020 11:04:50 AM

Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
3	043	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	044	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	045	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-1:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
1	001	-	-	-	-	ER-0:...
	002	-	-	-	-	ER-0:...
	003	-	-	-	-	ER-0:...
	004	-	-	-	-	ER-0:...
	005	-	-	-	-	ER-0:...
	006	-	-	-	-	ER-0:...
	007	-	-	-	-	ER-0:...
	008	-	-	-	-	ER-0:...
	009	-	-	-	-	ER-0:...
	010	-	-	-	-	ER-0:...
	011	-	-	-	-	ER-0:...
	012	-	-	-	-	ER-0:...
	013	-	-	-	-	ER-0:...
	014	-	-	-	-	ER-0:...
	015	-	-	-	-	ER-0:...
2	016	-	-	-	-	ER-0:...
	017	-	-	-	-	ER-0:...
	018	ER-0:...	ER-0:...	-	-	ER-0:...
	019	ER-0:...	ER-0:...	-	-	ER-0:...
	020	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	021	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...

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Study: 20GR142

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
2	022	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	023	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	024	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	025	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	026	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	027	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	028	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	029	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	030	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
3	031	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	032	ER-1:...	ER-0:...	-	-	ER-0:...
	033	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	034	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	035	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	036	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	037	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	038	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	039	ER-0:...	ER-0:...	-	-	ER-0:...
	040	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	041	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	042	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Document 2

Dermal Assessment Left/Right Report with Individual Values

Printed: 20 Aug 2020 11:04:50 AM

Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
3	043	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	044	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	045	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
1	001	ER-0:...	ER-0:...	-	-	-
	002	ER-0:...	ER-0:...	-	-	-
	003	ER-0:...	ER-0:...	-	-	-
	004	ER-0:...	ER-0:...	-	-	-
	005	ER-0:...	ER-0:...	-	-	-
	006	ER-0:...	ER-0:...	-	-	-
	007	ER-0:...	ER-0:...	-	-	-
	008	ER-0:...	ER-0:...	-	-	-
	009	ER-0:...	ER-0:...	-	-	-
	010	ER-0:...	ER-0:...	-	-	-
	011	ER-0:...	ER-0:...	-	-	-
	012	ER-0:...	ER-0:...	-	-	-
	013	ER-0:...	ER-0:...	-	-	-
	014	ER-0:...	ER-0:...	-	-	-
	015	ER-0:...	ER-0:...	-	-	-
2	016	ER-0:...	ER-0:...	ER-0:...	-	-
	017	ER-0:...	ER-0:...	-	-	-
	018	ER-0:...	ER-0:...	ER-0:...	-	-
	019	ER-0:...	ER-0:...	ER-0:...	-	-
	020	ER-0:...	ER-0:...	ER-0:...	-	-
	021	ER-0:...	ER-0:...	ER-0:...	-	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
2	022	ER-0:...	ER-0:...	ER-0:...	-	-
	023	ER-0:...	ER-0:...	ER-0:...	-	-
	024	ER-0:...	ER-0:...	ER-0:...	-	-
	025	ER-0:...	ER-0:...	ER-0:...	-	-
	026	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	027	ER-0:...	ER-0:...	ER-0:...	ER-0:...	-
	028	ER-0:...	ER-0:...	ER-0:...	ER-0:...	-
	029	ER-0:...	ER-0:...	-	-	-
	030	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
3	031	ER-0:...	ER-0:...	ER-1:...	-	-
	032	ER-0:...	ER-0:...	-	-	-
	033	ER-0:...	ER-0:...	ER-1:...	-	-
	034	ER-0:...	ER-0:...	ER-0:...	-	-
	035	ER-0:...	ER-0:...	ER-0:...	-	-
	036	ER-0:...	ER-0:...	ER-0:...	-	-
	037	ER-0:...	ER-0:...	ER-0:...	-	-
	038	ER-0:...	ER-0:...	ER-0:...	-	-
	039	ER-0:...	ER-0:...	ER-0:...	-	-
	040	ER-0:...	ER-0:...	ER-0:...	-	-
	041	ER-1:...	ER-0:...	ER-1:...	ER-0:...	ER-0:...
	042	ER-0:...	ER-0:...	ER-0:...	ER-0:...	-

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Document 2

Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
3	043	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	044	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	045	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
1	001	-
	002	-
	003	-
	004	-
	005	-
	006	-
	007	-
	008	-
	009	-
	010	-
	011	-
	012	-
	013	-
	014	-
	015	-
2	016	-
	017	-
	018	-
	019	-
	020	-
	021	-

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Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
2	022	-
	023	-
	024	-
	025	-
	026	ER-0:...
	027	-
	028	-
	029	-
	030	ER-0:...
3	031	-
	032	-
	033	-
	034	-
	035	-
	036	-
	037	-
	038	-
	039	-
	040	-
	041	ER-0:...
	042	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Males

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
3	043	ER-0:...
	044	ER-0:...
	045	ER-0:...

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StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
1	046	ER-0:...	ER-0:...	ER-0:...	-	-
	047	ER-0:...	ER-0:...	ER-0:...	-	-
	048	ER-0:...	ER-0:...	ER-0:...	-	-
	049	ER-0:...	ER-0:...	ER-0:...	-	-
	050	ER-0:...	ER-0:...	ER-0:...	-	-
	051	ER-0:...	ER-0:...	ER-0:...	-	-
	052	ER-0:...	ER-0:...	ER-0:...	-	-
	053	ER-0:...	ER-0:...	ER-0:...	-	-
	054	ER-0:...	ER-0:...	ER-0:...	-	-
	055	ER-0:...	ER-0:...	ER-0:...	-	-
	056	ER-0:...	ER-0:...	ER-0:...	-	-
	057	ER-0:...	ER-0:...	ER-0:...	-	-
	058	ER-0:...	ER-0:...	ER-0:...	-	-
	059	ER-0:...	ER-0:...	ER-0:...	-	-
	060	ER-0:...	ER-0:...	ER-0:...	-	-
2	061	ER-0:...	ER-0:...	ER-0:...	-	-
	062	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	063	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-0:...
	064	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	065	ER-0:...	ER-0:...	ER-0:...	-	-
	066	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
2	067	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	068	ER-0:...	ER-0:...	ER-0:...	-	-
	069	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	070	ER-0:...	ER-0:...	ER-0:...	-	-
	071	ER-0:...	ER-0:...	ER-1:...	-	-
	072	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	073	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	074	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	075	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
3	076	ER-0:...	ER-0:...	ER-1:...	-	-
	077	ER-0:...	ER-0:...	ER-1:...	-	-
	078	ER-0:...	ER-0:...	ER-1:...	-	-
	079	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	080	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	081	ER-0:...	ER-0:...	ER-1:...	-	-
	082	ER-0:...	ER-0:...	ER-1:...	-	-
	083	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	084	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	085	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	086	ER-0:...	ER-0:...	ER-1:...	-	-
	087	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
3	088	ER-0:...	ER-0:...	ER-1:...	ER-1:...	ER-1:...
	089	ER-0:...	ER-0:...	ER-1:...	-	-
	090	ER-0:...	ER-0:...	ER-1:...	-	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Document 2

Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
1	046	-	-	ER-0:...	ER-0:...	ER-0:...
	047	-	-	ER-0:...	ER-0:...	ER-0:...
	048	-	-	ER-0:...	ER-0:...	ER-0:...
	049	-	-	ER-0:...	ER-0:...	ER-0:...
	050	-	-	ER-0:...	ER-0:...	ER-0:...
	051	-	-	ER-0:...	ER-0:...	ER-0:...
	052	-	-	ER-0:...	ER-0:...	ER-0:...
	053	-	-	ER-0:...	ER-0:...	ER-0:...
	054	-	-	ER-0:...	ER-0:...	ER-0:...
	055	-	-	ER-0:...	ER-0:...	ER-0:...
	056	-	-	ER-0:...	ER-0:...	ER-0:...
	057	-	-	ER-0:...	ER-0:...	ER-0:...
	058	-	-	ER-0:...	ER-0:...	ER-0:...
	059	-	-	ER-0:...	ER-0:...	ER-0:...
	060	-	-	ER-0:...	ER-0:...	ER-0:...
2	061	-	-	ER-0:...	ER-0:...	ER-1:...
	062	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	063	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-1:...
	064	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	065	-	-	ER-0:...	ER-0:...	ER-1:...
	066	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
2	067	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	068	-	-	ER-0:...	ER-0:...	ER-1:...
	069	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	070	-	-	ER-0:...	ER-0:...	ER-1:...
	071	-	-	ER-0:...	ER-0:...	ER-1:...
	072	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	073	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	074	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	075	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
3	076	-	-	ER-0:...	ER-0:...	ER-1:...
	077	-	-	ER-0:...	ER-0:...	ER-1:...
	078	-	-	ER-0:...	ER-0:...	ER-1:...
	079	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	080	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	081	-	-	ER-0:...	ER-0:...	ER-1:...
	082	-	-	ER-0:...	ER-0:...	ER-1:...
	083	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	084	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	085	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	086	-	-	ER-0:...	ER-0:...	ER-1:...
	087	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
3	088	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-1:...
	089	-	-	ER-0:...	ER-0:...	ER-1:...
	090	-	-	ER-0:...	ER-0:...	ER-1:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Document 2

Study: 20GR142
StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY
Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
1	046	-	-	-	-	ER-0:...
	047	-	-	-	-	ER-0:...
	048	-	-	-	-	ER-0:...
	049	-	-	-	-	ER-0:...
	050	-	-	-	-	ER-0:...
	051	-	-	-	-	ER-0:...
	052	-	-	-	-	ER-0:...
	053	-	-	-	-	ER-0:...
	054	-	-	-	-	ER-0:...
	055	-	-	-	-	ER-0:...
	056	-	-	-	-	ER-0:...
	057	-	-	-	-	ER-0:...
	058	-	-	-	-	ER-0:...
	059	-	-	-	-	ER-0:...
	060	-	-	-	-	ER-0:...
2	061	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	062	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	063	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	064	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	065	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	066	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Study: 20GR142

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
2	067	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	068	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	069	ER-1:...	ER-0:...	-	-	ER-0:...
	070	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	071	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	072	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	073	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	074	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	075	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
3	076	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	077	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	078	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	079	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	080	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	081	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	082	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	083	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	084	ER-1:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	085	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...
	086	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	087	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
3	088	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	089	ER-1:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	090	ER-1:...	ER-1:...	ER-1:...	ER-0:...	ER-0:...

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Study: 20GR142
StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY
Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
1	046	ER-0:...	ER-0:...	-	-	-
	047	ER-0:...	ER-0:...	-	-	-
	048	ER-0:...	ER-0:...	-	-	-
	049	ER-0:...	ER-0:...	-	-	-
	050	ER-0:...	ER-0:...	-	-	-
	051	ER-0:...	ER-0:...	-	-	-
	052	ER-0:...	ER-0:...	-	-	-
	053	ER-0:...	ER-0:...	-	-	-
	054	ER-0:...	ER-0:...	-	-	-
	055	ER-0:...	ER-0:...	-	-	-
	056	ER-0:...	ER-0:...	-	-	-
	057	ER-0:...	ER-0:...	-	-	-
	058	ER-0:...	ER-0:...	-	-	-
	059	ER-0:...	ER-0:...	-	-	-
	060	ER-0:...	ER-0:...	-	-	-
2	061	ER-0:...	ER-0:...	ER-0:...	-	-
	062	ER-0:...	ER-1:...	ER-1:...	-	-
	063	ER-0:...	ER-1:...	ER-1:...	-	-
	064	ER-0:...	ER-1:...	ER-0:...	-	-
	065	ER-0:...	ER-1:...	ER-0:...	-	-
	066	ER-0:...	ER-1:...	ER-0:...	-	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
2	067	ER-0:...	ER-1:...	ER-0:...	-	-
	068	ER-0:...	ER-1:...	ER-0:...	-	-
	069	ER-0:...	ER-1:...	ER-0:...	-	-
	070	ER-0:...	ER-0:...	ER-0:...	-	-
	071	ER-0:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	072	ER-0:...	ER-1:...	ER-0:...	ER-1:...	ER-0:...
	073	ER-0:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	074	ER-0:...	ER-0:...	ER-0:...	ER-0:...	ER-0:...
	075	ER-0:...	ER-1:...	ER-1:...	ER-1:...	ER-0:...
3	076	ER-0:...	ER-1:...	ER-1:...	-	-
	077	ER-0:...	ER-1:...	ER-1:...	-	-
	078	ER-0:...	ER-1:...	ER-1:...	-	-
	079	ER-0:...	ER-1:...	ER-0:...	-	-
	080	ER-0:...	ER-1:...	ER-1:...	-	-
	081	ER-0:...	ER-1:...	ER-1:...	-	-
	082	ER-0:...	ER-1:...	ER-1:...	-	-
	083	ER-0:...	ER-1:...	ER-0:...	-	-
	084	ER-0:...	ER-1:...	ER-1:...	-	-
	085	ER-0:...	ER-1:...	ER-1:...	-	-
	086	ER-0:...	ER-1:...	ER-0:...	ER-0:...	ER-0:...
	087	ER-0:...	ER-1:...	ER-1:...	ER-1:...	ER-0:...

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Document 2

Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
3	088	ER-0:...	ER-1:...	ER-1:...	ER-1:...	ER-1:...
	089	ER-0:...	ER-1:...	ER-1:...	ER-1:...	ER-0:...
	090	ER-0:...	ER-1:...	ER-1:...	ER-1:...	ER-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
1	046	-
	047	-
	048	-
	049	-
	050	-
	051	-
	052	-
	053	-
	054	-
	055	-
	056	-
	057	-
	058	-
	059	-
	060	-
2	061	-
	062	-
	063	-
	064	-
	065	-
	066	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
2	067	-
	068	-
	069	-
	070	-
	071	ER-0:...
	072	ER-0:...
	073	ER-0:...
	074	ER-0:...
	075	ER-0:...
3	076	-
	077	-
	078	-
	079	-
	080	-
	081	-
	082	-
	083	-
	084	-
	085	-
	086	ER-0:...
	087	ER-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Left(ERL)

Females

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
3	088	ER-0:...
	089	ER-0:...
	090	ER-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Right(ERR)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
1	001	ER-0:...	ER-0:...
	002	ER-0:...	ER-0:...
	003	ER-0:...	ER-0:...
	004	ER-0:...	ER-0:...
	005	ER-0:...	ER-0:...
	006	ER-0:...	ER-0:...
	007	ER-0:...	ER-0:...
	008	ER-0:...	-
	009	ER-0:...	ER-0:...
	010	ER-0:...	-
	011	ER-0:...	-
	012	ER-0:...	-
	013	ER-0:...	-
	014	ER-0:...	-
	015	ER-0:...	-
2	016	ER-0:...	-
	017	ER-0:...	-
	018	ER-0:...	-
	019	ER-0:...	-
	020	ER-0:...	-
	021	ER-0:...	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Right(ERR)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
2	022	ER-0:...	-
	023	ER-0:...	-
	024	ER-0:...	-
	025	ER-0:...	-
	026	ER-0:...	-
	027	ER-0:...	-
	028	ER-0:...	-
	029	ER-0:...	-
	030	ER-0:...	-
3	031	ER-0:...	-
	032	ER-0:...	-
	033	ER-0:...	-
	034	ER-0:...	-
	035	ER-0:...	-
	036	ER-0:...	-
	037	ER-0:...	-
	038	ER-0:...	-
	039	ER-0:...	-
	040	ER-0:...	-
	041	ER-0:...	-
	042	ER-0:...	-

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Right(ERR)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
3	043	ER-0:...	-
	044	ER-0:...	-
	045	ER-0:...	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Right(ERR)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
1	046	ER-0:...	ER-0:...
	047	ER-0:...	ER-0:...
	048	ER-0:...	ER-0:...
	049	ER-0:...	ER-0:...
	050	ER-0:...	ER-0:...
	051	ER-0:...	ER-0:...
	052	ER-0:...	ER-0:...
	053	ER-0:...	ER-0:...
	054	ER-0:...	ER-0:...
	055	ER-0:...	ER-0:...
	056	ER-0:...	ER-0:...
	057	ER-0:...	ER-0:...
	058	ER-0:...	ER-0:...
	059	ER-0:...	-
	060	ER-0:...	-
2	061	ER-0:...	-
	062	ER-0:...	-
	063	ER-0:...	-
	064	ER-0:...	-
	065	ER-0:...	-
	066	ER-0:...	-

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Right(ERR)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
2	067	ER-0:...	-
	068	ER-0:...	-
	069	ER-0:...	-
	070	ER-0:...	-
	071	ER-0:...	-
	072	ER-0:...	-
	073	ER-0:...	-
	074	ER-0:...	-
	075	ER-0:...	-
3	076	ER-0:...	-
	077	ER-0:...	-
	078	ER-0:...	-
	079	ER-0:...	-
	080	ER-0:...	-
	081	ER-0:...	-
	082	ER-0:...	-
	083	ER-0:...	-
	084	ER-0:...	-
	085	ER-0:...	-
	086	ER-0:...	-
	087	ER-0:...	-

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Study: 20GR142

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Erythema Grade-Right(ERR)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
3	088	ER-0:...	-
	089	ER-0:...	-
	090	ER-0:...	-

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Study: 20GR142
StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY
Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
1	001	ED-0:...	ED-0:...	ED-0:...	-	-
	002	ED-0:...	ED-0:...	ED-0:...	-	-
	003	ED-0:...	ED-0:...	ED-0:...	-	-
	004	ED-0:...	ED-0:...	ED-0:...	-	-
	005	ED-0:...	ED-0:...	ED-0:...	-	-
	006	ED-0:...	ED-0:...	ED-0:...	-	-
	007	ED-0:...	ED-0:...	ED-0:...	-	-
	008	ED-0:...	ED-0:...	ED-0:...	-	-
	009	ED-0:...	ED-0:...	ED-0:...	-	-
	010	ED-0:...	ED-0:...	ED-0:...	-	-
	011	ED-0:...	ED-0:...	ED-0:...	-	-
	012	ED-0:...	ED-0:...	ED-0:...	-	-
	013	ED-0:...	ED-0:...	ED-0:...	-	-
	014	ED-0:...	ED-0:...	ED-0:...	-	-
	015	ED-0:...	ED-0:...	ED-0:...	-	-
2	016	ED-0:...	ED-0:...	ED-0:...	-	-
	017	ED-0:...	ED-0:...	ED-0:...	-	-
	018	ED-0:...	ED-0:...	ED-0:...	-	-
	019	ED-0:...	ED-0:...	ED-1:...	-	-
	020	ED-0:...	ED-0:...	ED-1:...	-	-
	021	ED-0:...	ED-0:...	ED-2:...	ED-1:...	ED-0:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
2	022	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	023	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	024	ED-0:...	ED-0:...	ED-0:...	-	-
	025	ED-0:...	ED-0:...	ED-1:...	-	-
	026	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	027	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	028	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	029	ED-0:...	ED-0:...	ED-1:...	-	-
	030	ED-0:...	ED-0:...	ED-1:...	-	-
3	031	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	032	ED-0:...	ED-0:...	ED-0:...	-	-
	033	ED-0:...	ED-0:...	ED-1:...	-	-
	034	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-1:...
	035	ED-0:...	ED-0:...	ED-0:...	-	-
	036	ED-0:...	ED-0:...	ED-1:...	-	-
	037	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	038	ED-0:...	ED-0:...	ED-1:...	-	-
	039	ED-0:...	ED-0:...	ED-1:...	-	-
	040	ED-0:...	ED-0:...	ED-1:...	-	-
	041	ED-0:...	ED-0:...	ED-1:...	-	-
	042	ED-0:...	ED-0:...	ED-1:...	-	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
3	043	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	044	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	045	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...

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Pfizer

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
1	001	-	-	ED-0:...	ED-0:...	ED-0:...
	002	-	-	ED-0:...	ED-0:...	ED-0:...
	003	-	-	ED-0:...	ED-0:...	ED-0:...
	004	-	-	ED-0:...	ED-0:...	ED-0:...
	005	-	-	ED-0:...	ED-0:...	ED-0:...
	006	-	-	ED-0:...	ED-0:...	ED-0:...
	007	-	-	ED-0:...	ED-0:...	ED-0:...
	008	-	-	ED-0:...	ED-0:...	ED-0:...
	009	-	-	ED-0:...	ED-0:...	ED-0:...
	010	-	-	ED-0:...	ED-0:...	ED-0:...
	011	-	-	ED-0:...	ED-0:...	ED-0:...
	012	-	-	ED-0:...	ED-0:...	ED-0:...
	013	-	-	ED-0:...	ED-0:...	ED-0:...
	014	-	-	ED-0:...	ED-0:...	ED-0:...
	015	-	-	ED-0:...	ED-0:...	ED-0:...
2	016	-	-	ED-0:...	ED-0:...	ED-0:...
	017	-	-	ED-0:...	ED-0:...	ED-0:...
	018	-	-	ED-0:...	ED-0:...	ED-2:...
	019	-	-	ED-0:...	ED-0:...	ED-2:...
	020	-	-	ED-0:...	ED-0:...	ED-2:...
	021	-	-	ED-0:...	ED-0:...	ED-2:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Document 2

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
2	022	-	-	ED-0:...	ED-0:...	ED-3:...
	023	-	-	ED-0:...	ED-0:...	ED-3:...
	024	-	-	ED-0:...	ED-0:...	ED-3:...
	025	-	-	ED-0:...	ED-0:...	ED-3:...
	026	-	-	ED-0:...	ED-0:...	ED-3:...
	027	-	-	ED-0:...	ED-0:...	ED-2:...
	028	-	-	ED-0:...	ED-0:...	ED-3:...
	029	-	-	ED-0:...	ED-0:...	ED-3:...
	030	-	-	ED-0:...	ED-0:...	ED-2:...
3	031	-	-	ED-0:...	ED-0:...	ED-3:...
	032	-	-	ED-0:...	ED-0:...	ED-2:...
	033	-	-	ED-0:...	ED-0:...	ED-3:...
	034	-	-	ED-0:...	ED-0:...	ED-2:...
	035	-	-	ED-0:...	ED-0:...	ED-3:...
	036	-	-	ED-0:...	ED-0:...	ED-2:...
	037	ED-2:...	ED-1:...	ED-0:...	ED-0:...	ED-3:...
	038	-	-	ED-0:...	ED-0:...	ED-3:...
	039	-	-	ED-0:...	ED-0:...	ED-2:...
	040	-	-	ED-0:...	ED-0:...	ED-3:...
	041	-	-	ED-0:...	ED-0:...	ED-3:...
	042	-	-	ED-0:...	ED-0:...	ED-3:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Study: 20GR142
StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY
Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
3	043	ED-2:...	ED-1:...	ED-0:...	ED-0:...	ED-3:...
	044	ED-2:...	ED-1:...	ED-0:...	ED-0:...	ED-3:...
	045	ED-2:...	ED-1:...	ED-0:...	ED-0:...	ED-3:...

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Document 2

Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
1	001	-	-	-	-	ED-0:...
	002	-	-	-	-	ED-0:...
	003	-	-	-	-	ED-0:...
	004	-	-	-	-	ED-0:...
	005	-	-	-	-	ED-0:...
	006	-	-	-	-	ED-0:...
	007	-	-	-	-	ED-0:...
	008	-	-	-	-	ED-0:...
	009	-	-	-	-	ED-0:...
	010	-	-	-	-	ED-0:...
	011	-	-	-	-	ED-0:...
	012	-	-	-	-	ED-0:...
	013	-	-	-	-	ED-0:...
	014	-	-	-	-	ED-0:...
	015	-	-	-	-	ED-0:...
2	016	-	-	-	-	ED-0:...
	017	-	-	-	-	ED-0:...
	018	ED-2:...	ED-1:...	-	-	ED-0:...
	019	ED-2:...	ED-1:...	-	-	ED-0:...
	020	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	021	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
2	022	ED-3:...	ED-2:...	ED-1:...	ED-1:...	ED-0:...
	023	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	024	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	025	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	026	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	027	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	028	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	029	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	030	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
3	031	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	032	ED-2:...	ED-1:...	-	-	ED-0:...
	033	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	034	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	035	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	036	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	037	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	038	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	039	ED-2:...	ED-1:...	-	-	ED-0:...
	040	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	041	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	042	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
3	043	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	044	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	045	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
1	001	ED-0:...	ED-0:...	-	-	-
	002	ED-0:...	ED-0:...	-	-	-
	003	ED-0:...	ED-0:...	-	-	-
	004	ED-0:...	ED-0:...	-	-	-
	005	ED-0:...	ED-0:...	-	-	-
	006	ED-0:...	ED-0:...	-	-	-
	007	ED-0:...	ED-0:...	-	-	-
	008	ED-0:...	ED-0:...	-	-	-
	009	ED-0:...	ED-0:...	-	-	-
	010	ED-0:...	ED-0:...	-	-	-
	011	ED-0:...	ED-0:...	-	-	-
	012	ED-0:...	ED-0:...	-	-	-
	013	ED-0:...	ED-0:...	-	-	-
	014	ED-0:...	ED-0:...	-	-	-
	015	ED-0:...	ED-0:...	-	-	-
2	016	ED-0:...	ED-2:...	ED-2:...	-	-
	017	ED-0:...	ED-0:...	-	-	-
	018	ED-0:...	ED-2:...	ED-2:...	-	-
	019	ED-0:...	ED-2:...	ED-2:...	-	-
	020	ED-0:...	ED-2:...	ED-2:...	-	-
	021	ED-0:...	ED-2:...	ED-2:...	-	-

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Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
2	022	ED-0:...	ED-2:...	ED-2:...	-	-
	023	ED-0:...	ED-2:...	ED-2:...	-	-
	024	ED-0:...	ED-2:...	ED-2:...	-	-
	025	ED-0:...	ED-2:...	ED-2:...	-	-
	026	ED-1:...	ED-2:...	ED-2:...	ED-2:...	ED-0:...
	027	ED-0:...	ED-3:...	ED-3:...	ED-1:...	-
	028	ED-0:...	ED-3:...	ED-3:...	ED-1:...	-
	029	ED-1:...	ED-1:...	-	-	-
	030	ED-0:...	ED-2:...	ED-2:...	ED-2:...	ED-1:...
3	031	ED-0:...	ED-2:...	ED-3:...	-	-
	032	ED-0:...	ED-1:...	-	-	-
	033	ED-0:...	ED-2:...	ED-2:...	-	-
	034	ED-0:...	ED-2:...	ED-2:...	-	-
	035	ED-0:...	ED-2:...	ED-2:...	-	-
	036	ED-1:...	ED-2:...	ED-2:...	-	-
	037	ED-1:...	ED-2:...	ED-2:...	-	-
	038	ED-1:...	ED-2:...	ED-2:...	-	-
	039	ED-0:...	ED-2:...	ED-2:...	-	-
	040	ED-0:...	ED-2:...	ED-2:...	-	-
	041	ED-1:...	ED-3:...	ED-3:...	ED-2:...	ED-0:...
	042	ED-0:...	ED-2:...	ED-2:...	ED-1:...	-

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Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
3	043	ED-0:...	ED-3:...	ED-3:...	ED-2:...	ED-0:...
	044	ED-1:...	ED-3:...	ED-3:...	ED-2:...	ED-0:...
	045	ED-0:...	ED-2:...	ED-2:...	ED-2:...	ED-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
1	001	-
	002	-
	003	-
	004	-
	005	-
	006	-
	007	-
	008	-
	009	-
	010	-
	011	-
	012	-
	013	-
	014	-
	015	-
2	016	-
	017	-
	018	-
	019	-
	020	-
	021	-

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
2	022	-
	023	-
	024	-
	025	-
	026	ED-1:...
	027	-
	028	-
	029	-
	030	ED-1:...
3	031	-
	032	-
	033	-
	034	-
	035	-
	036	-
	037	-
	038	-
	039	-
	040	-
	041	ED-1:...
	042	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Males

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
3	043	ED-0:...
	044	ED-0:...
	045	ED-0:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Dermal Assessment Left/Right Report with Individual Values

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Study: 20GR142

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
1	046	ED-0:...	ED-0:...	ED-0:...	-	-
	047	ED-0:...	ED-0:...	ED-0:...	-	-
	048	ED-0:...	ED-0:...	ED-0:...	-	-
	049	ED-0:...	ED-0:...	ED-0:...	-	-
	050	ED-0:...	ED-0:...	ED-0:...	-	-
	051	ED-0:...	ED-0:...	ED-0:...	-	-
	052	ED-0:...	ED-0:...	ED-0:...	-	-
	053	ED-0:...	ED-0:...	ED-0:...	-	-
	054	ED-0:...	ED-0:...	ED-0:...	-	-
	055	ED-0:...	ED-0:...	ED-0:...	-	-
	056	ED-0:...	ED-0:...	ED-0:...	-	-
	057	ED-0:...	ED-0:...	ED-0:...	-	-
	058	ED-0:...	ED-0:...	ED-0:...	-	-
	059	ED-0:...	ED-0:...	ED-0:...	-	-
	060	ED-0:...	ED-0:...	ED-0:...	-	-
2	061	ED-0:...	ED-0:...	ED-1:...	-	-
	062	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	063	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	064	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	065	ED-0:...	ED-0:...	ED-1:...	-	-
	066	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
2	067	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	068	ED-0:...	ED-0:...	ED-1:...	-	-
	069	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	070	ED-0:...	ED-0:...	ED-1:...	-	-
	071	ED-0:...	ED-0:...	ED-1:...	-	-
	072	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	073	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	074	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	075	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
3	076	ED-0:...	ED-0:...	ED-1:...	-	-
	077	ED-0:...	ED-0:...	ED-1:...	-	-
	078	ED-0:...	ED-0:...	ED-1:...	-	-
	079	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	080	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	081	ED-0:...	ED-0:...	ED-1:...	-	-
	082	ED-0:...	ED-0:...	ED-1:...	-	-
	083	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	084	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	085	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	086	ED-0:...	ED-0:...	ED-1:...	-	-
	087	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Document 2

Dermal Assessment Left/Right Report with Individual Values

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Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 3 Session: S4-48 HPD	Day: 4 Session: S5-72 HPD
3	088	ED-0:...	ED-0:...	ED-2:...	ED-2:...	ED-2:...
	089	ED-0:...	ED-0:...	ED-1:...	-	-
	090	ED-0:...	ED-1:...	ED-1:...	-	-

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
1	046	-	-	ED-0:...	ED-0:...	ED-0:...
	047	-	-	ED-0:...	ED-0:...	ED-0:...
	048	-	-	ED-0:...	ED-0:...	ED-0:...
	049	-	-	ED-0:...	ED-0:...	ED-0:...
	050	-	-	ED-0:...	ED-0:...	ED-0:...
	051	-	-	ED-0:...	ED-0:...	ED-0:...
	052	-	-	ED-0:...	ED-0:...	ED-0:...
	053	-	-	ED-0:...	ED-0:...	ED-0:...
	054	-	-	ED-0:...	ED-0:...	ED-0:...
	055	-	-	ED-0:...	ED-0:...	ED-0:...
	056	-	-	ED-0:...	ED-0:...	ED-0:...
	057	-	-	ED-0:...	ED-0:...	ED-0:...
	058	-	-	ED-0:...	ED-0:...	ED-0:...
	059	-	-	ED-0:...	ED-0:...	ED-0:...
	060	-	-	ED-0:...	ED-0:...	ED-0:...
2	061	-	-	ED-0:...	ED-0:...	ED-2:...
	062	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	063	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
	064	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
	065	-	-	ED-0:...	ED-0:...	ED-3:...
	066	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
2	067	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	068	-	-	ED-0:...	ED-0:...	ED-3:...
	069	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
	070	-	-	ED-0:...	ED-0:...	ED-3:...
	071	-	-	ED-0:...	ED-0:...	ED-3:...
	072	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	073	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
	074	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	075	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
3	076	-	-	ED-0:...	ED-0:...	ED-3:...
	077	-	-	ED-0:...	ED-0:...	ED-3:...
	078	-	-	ED-0:...	ED-0:...	ED-3:...
	079	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	080	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	081	-	-	ED-0:...	ED-0:...	ED-2:...
	082	-	-	ED-0:...	ED-0:...	ED-3:...
	083	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	084	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
	085	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...
	086	-	-	ED-0:...	ED-0:...	ED-2:...
	087	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-3:...

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Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 6 Session: S6-120 HPD	Day: 7 Session: S7-144 HPD	Day: 8 Session: S1-Predose	Session: S2-4 HPD	Day: 9 Session: S3-24 HPD
3	088	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-2:...
	089	-	-	ED-0:...	ED-0:...	ED-2:...
	090	-	-	ED-0:...	ED-0:...	ED-2:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
1	046	-	-	-	-	ED-0:...
	047	-	-	-	-	ED-0:...
	048	-	-	-	-	ED-0:...
	049	-	-	-	-	ED-0:...
	050	-	-	-	-	ED-0:...
	051	-	-	-	-	ED-0:...
	052	-	-	-	-	ED-0:...
	053	-	-	-	-	ED-0:...
	054	-	-	-	-	ED-0:...
	055	-	-	-	-	ED-0:...
	056	-	-	-	-	ED-0:...
	057	-	-	-	-	ED-0:...
	058	-	-	-	-	ED-0:...
	059	-	-	-	-	ED-0:...
	060	-	-	-	-	ED-0:...
2	061	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	062	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	063	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	064	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	065	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	066	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
2	067	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	068	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	069	ED-2:...	ED-1:...	-	-	ED-0:...
	070	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	071	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	072	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	073	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	074	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	075	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
3	076	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	077	ED-3:...	ED-3:...	ED-2:...	ED-0:...	ED-0:...
	078	ED-3:...	ED-3:...	ED-2:...	ED-1:...	ED-0:...
	079	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	080	ED-3:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	081	ED-3:...	ED-2:...	ED-0:...	ED-0:...	ED-0:...
	082	ED-3:...	ED-2:...	ED-0:...	ED-0:...	ED-0:...
	083	ED-3:...	ED-3:...	ED-0:...	ED-0:...	ED-0:...
	084	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	085	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	086	ED-2:...	ED-2:...	ED-1:...	ED-0:...	ED-0:...
	087	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 10 Session: S4-48 HPD	Day: 11 Session: S5-72 HPD	Day: 13 Session: S6-120 HPD	Day: 14 Session: S7-144 HPD	Day: 15 Session: S1-Predose
3	088	ED-3:...	ED-3:...	ED-1:...	ED-0:...	ED-0:...
	089	ED-2:...	ED-2:...	ED-0:...	ED-0:...	ED-0:...
	090	ED-2:...	ED-2:...	ED-2:...	ED-0:...	ED-0:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
1	046	ED-0:...	ED-0:...	-	-	-
	047	ED-0:...	ED-0:...	-	-	-
	048	ED-0:...	ED-0:...	-	-	-
	049	ED-0:...	ED-0:...	-	-	-
	050	ED-0:...	ED-0:...	-	-	-
	051	ED-0:...	ED-0:...	-	-	-
	052	ED-0:...	ED-0:...	-	-	-
	053	ED-0:...	ED-0:...	-	-	-
	054	ED-0:...	ED-0:...	-	-	-
	055	ED-0:...	ED-0:...	-	-	-
	056	ED-0:...	ED-0:...	-	-	-
	057	ED-0:...	ED-0:...	-	-	-
	058	ED-0:...	ED-0:...	-	-	-
	059	ED-0:...	ED-0:...	-	-	-
	060	ED-0:...	ED-0:...	-	-	-
2	061	ED-0:...	ED-2:...	ED-2:...	-	-
	062	ED-0:...	ED-3:...	ED-3:...	-	-
	063	ED-0:...	ED-3:...	ED-3:...	-	-
	064	ED-0:...	ED-3:...	ED-2:...	-	-
	065	ED-0:...	ED-2:...	ED-2:...	-	-
	066	ED-0:...	ED-3:...	ED-3:...	-	-

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Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
2	067	ED-0:...	ED-3:...	ED-2:...	-	-
	068	ED-0:...	ED-2:...	ED-2:...	-	-
	069	ED-0:...	ED-3:...	ED-2:...	-	-
	070	ED-0:...	ED-2:...	ED-2:...	-	-
	071	ED-0:...	ED-3:...	ED-3:...	ED-2:...	ED-1:...
	072	ED-0:...	ED-3:...	ED-3:...	ED-3:...	ED-1:...
	073	ED-0:...	ED-2:...	ED-2:...	ED-2:...	ED-1:...
	074	ED-0:...	ED-2:...	ED-1:...	ED-2:...	ED-1:...
	075	ED-0:...	ED-3:...	ED-3:...	ED-3:...	ED-0:...
3	076	ED-0:...	ED-3:...	ED-3:...	-	-
	077	ED-0:...	ED-3:...	ED-3:...	-	-
	078	ED-0:...	ED-3:...	ED-3:...	-	-
	079	ED-0:...	ED-3:...	ED-2:...	-	-
	080	ED-0:...	ED-3:...	ED-3:...	-	-
	081	ED-0:...	ED-3:...	ED-3:...	-	-
	082	ED-0:...	ED-3:...	ED-2:...	-	-
	083	ED-0:...	ED-3:...	ED-3:...	-	-
	084	ED-0:...	ED-3:...	ED-2:...	-	-
	085	ED-0:...	ED-2:...	ED-3:...	-	-
	086	ED-0:...	ED-2:...	ED-2:...	ED-2:...	ED-1:...
	087	ED-0:...	ED-3:...	ED-3:...	ED-3:...	ED-1:...

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Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Dosing Day: 15 Session: S2-4 HPD	Day: 16 Session: S3-24 HPD	Day: 17 Session: S4-48 HPD	Recovery Day: 1 Session: S5-72 HPD	Day: 3 Session: S6-120 HPD
3	088	ED-0:...	ED-3:...	ED-3:...	ED-3:...	ED-1:...
	089	ED-0:...	ED-2:...	ED-2:...	ED-3:...	ED-0:...
	090	ED-0:...	ED-2:...	ED-2:...	ED-2:...	ED-1:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
1	046	-
	047	-
	048	-
	049	-
	050	-
	051	-
	052	-
	053	-
	054	-
	055	-
	056	-
	057	-
	058	-
	059	-
	060	-
2	061	-
	062	-
	063	-
	064	-
	065	-
	066	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
2	067	-
	068	-
	069	-
	070	-
	071	ED-0:...
	072	ED-0:...
	073	ED-0:...
	074	ED-0:...
	075	ED-0:...
3	076	-
	077	-
	078	-
	079	-
	080	-
	081	-
	082	-
	083	-
	084	-
	085	-
	086	ED-0:...
	087	ED-0:...

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Rat/Wistar Han Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Left(EDL)

Females

Group #	Animal #	Recovery Day: 4 Session: S7-144 HPD
3	088	ED-0:...
	089	ED-0:...
	090	ED-0:...

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Right(EDR)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
1	001	ED-0:...	ED-0:...
	002	ED-0:...	ED-0:...
	003	ED-0:...	ED-0:...
	004	ED-0:...	ED-0:...
	005	ED-0:...	ED-0:...
	006	ED-0:...	ED-0:...
	007	ED-0:...	ED-0:...
	008	ED-0:...	-
	009	ED-0:...	ED-0:...
	010	ED-0:...	-
	011	ED-0:...	-
	012	ED-0:...	-
	013	ED-0:...	-
	014	ED-0:...	-
	015	ED-0:...	-
2	016	ED-0:...	-
	017	ED-0:...	-
	018	ED-0:...	-
	019	ED-0:...	-
	020	ED-0:...	-
	021	ED-0:...	-

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Right(EDR)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
2	022	ED-0:...	-
	023	ED-0:...	-
	024	ED-0:...	-
	025	ED-0:...	-
	026	ED-0:...	-
	027	ED-0:...	-
	028	ED-0:...	-
	029	ED-0:...	-
	030	ED-0:...	-
3	031	ED-0:...	-
	032	ED-0:...	-
	033	ED-0:...	-
	034	ED-0:...	-
	035	ED-0:...	-
	036	ED-0:...	-
	037	ED-0:...	-
	038	ED-0:...	-
	039	ED-0:...	-
	040	ED-0:...	-
	041	ED-0:...	-
	042	ED-0:...	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Dermal Assessment Left/Right Report with Individual Values

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Pfizer

Pristima® Version 7.4.3 Build 25

Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Right(EDR)

Males

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
3	043	ED-0:...	-
	044	ED-0:...	-
	045	ED-0:...	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Right(EDR)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
1	046	ED-0:...	ED-0:...
	047	ED-0:...	ED-0:...
	048	ED-0:...	ED-0:...
	049	ED-0:...	ED-0:...
	050	ED-0:...	ED-0:...
	051	ED-0:...	ED-0:...
	052	ED-0:...	ED-0:...
	053	ED-0:...	ED-0:...
	054	ED-0:...	ED-0:...
	055	ED-0:...	ED-0:...
	056	ED-0:...	ED-0:...
	057	ED-0:...	ED-0:...
	058	ED-0:...	ED-0:...
	059	ED-0:...	-
	060	ED-0:...	-
2	061	ED-0:...	-
	062	ED-0:...	-
	063	ED-0:...	-
	064	ED-0:...	-
	065	ED-0:...	-
	066	ED-0:...	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Right(EDR)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
2	067	ED-0:...	-
	068	ED-0:...	-
	069	ED-0:...	-
	070	ED-0:...	-
	071	ED-0:...	-
	072	ED-0:...	-
	073	ED-0:...	-
	074	ED-0:...	-
	075	ED-0:...	-
3	076	ED-0:...	-
	077	ED-0:...	-
	078	ED-0:...	-
	079	ED-0:...	-
	080	ED-0:...	-
	081	ED-0:...	-
	082	ED-0:...	-
	083	ED-0:...	-
	084	ED-0:...	-
	085	ED-0:...	-
	086	ED-0:...	-
	087	ED-0:...	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Edema Grade-Right(EDR)

Females

Group #	Animal #	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD
3	088	ED-0:...	-
	089	ED-0:...	-
	090	ED-0:...	-

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Body Temperature Report with Individual Values

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Males

Group #	Animal #	PID Day: 6 Session: S1-Predose	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 8 Session: S1-Predose
1	001	36.8	36.1	35.8	37.4	37.7
	002	36.2	35.9	36.0	38.8	37.7
	003	36.9	36.5	36.1	38.2	36.7
	004	36.0	37.8	36.4	38.7	36.9
	005	37.1	36.8	35.6	38.3	37.7
	006	36.5	37.1	36.8	38.1	36.7
	007	36.0	37.2	36.4	38.5	37.4
	008	36.9	37.8	35.6	38.1	37.6
	009	36.2	37.0	36.5	38.8	37.6
	010	37.5	37.2	35.6	38.2	36.9
	011	36.7	37.1	36.2	38.3	37.5
	012	36.5	36.9	35.2	38.3	36.6
	013	35.6	36.8	36.2	38.2	37.9
	014	37.8	37.1	35.2	38.5	37.7
	015	37.7	37.1	36.0	38.2	37.3
2	016	36.4	37.0	36.1	38.3	36.7
	017	36.8	36.9	36.1	39.2	37.1
	018	37.5	37.0	36.3	39.2	37.9
	019	36.0	36.8	37.0	38.7	36.9
	020	36.1	37.1	35.9	38.5	36.7
	021	36.0	36.9	35.9	39.3	36.9

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Males

Group #	Animal #	PID Day: 6 Session: S1-Predose	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 8 Session: S1-Predose
2	022	36.9	37.1	35.5	39.1	37.7
	023	36.6	37.1	35.8	38.4	36.9
	024	37.4	36.9	35.0	38.5	37.3
	025	37.5	38.5	35.1	39.1	38.4
	026	36.1	36.9	36.9	39.1	36.6
	027	37.7	36.8	36.7	38.8	36.9
	028	37.7	37.0	35.5	38.9	37.4
	029	36.3	37.1	36.6	38.4	36.8
	030	35.2	36.8	35.5	39.3	38.5
3	031	38.2	36.8	36.3	38.8	36.4
	032	36.3	37.0	36.1	39.4	36.6
	033	37.0	36.9	36.4	38.9	37.0
	034	37.9	36.9	35.6	38.6	36.4
	035	38.2	37.1	35.3	38.4	37.9
	036	36.8	37.2	36.2	38.7	37.1
	037	37.0	36.7	36.0	39.0	37.0
	038	36.2	37.0	35.7	39.2	37.6
	039	36.8	36.8	36.0	39.1	36.8
	040	36.0	37.4	36.2	39.0	37.6
	041	35.9	36.9	36.4	38.6	37.6
	042	36.0	36.7	36.4	38.8	37.4

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Males

Group #	Animal #	PID Day: 6 Session: S1-Predose	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 8 Session: S1-Predose
3	043	36.4	37.2	36.6	39.5	37.3
	044	36.3	37.0	35.9	39.8	38.0
	045	37.0	37.1	36.1	39.5	37.4

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Males

Group #	Animal #	Dosing Day: 8 Session: S2-4 HPD	Day: 9 Session: S3-24 HPD	Day: 15 Session: S1-Predose	Session: S2-4 HPD	Day: 16 Session: S3-24 HPD
1	001	34.6	37.0	37.6	36.8	37.3
	002	34.5	36.9	37.4	36.5	36.7
	003	34.7	37.1	37.8	37.2	37.2
	004	34.9	36.9	38.8	36.8	37.1
	005	36.3	37.0	38.0	37.7	36.9
	006	36.4	37.1	37.3	37.0	37.0
	007	35.5	36.9	37.4	36.8	37.1
	008	35.5	36.6	37.9	37.3	37.1
	009	36.2	36.3	37.9	36.9	37.3
	010	37.2	36.5	37.4	37.4	36.7
	011	36.4	36.8	38.6	37.0	37.0
	012	36.6	37.4	38.2	37.8	37.4
	013	36.8	37.6	37.6	37.5	37.0
	014	36.9	37.6	38.2	37.7	36.3
	015	37.2	37.6	37.9	38.0	36.7
2	016	36.0	39.0	37.4	37.5	38.6
	017	36.1	38.4	37.8	38.1	38.5
	018	36.0	37.5	38.5	38.8	38.4
	019	36.7	37.9	37.8	38.5	37.6
	020	37.2	38.1	37.2	37.9	37.5
	021	36.4	38.3	37.6	38.1	38.9

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Males

Group #	Animal #	Dosing Day: 8 Session: S2-4 HPD	Day: 9 Session: S3-24 HPD	Day: 15 Session: S1-Predose	Session: S2-4 HPD	Day: 16 Session: S3-24 HPD
2	022	35.1	37.8	37.9	38.4	38.5
	023	35.9	37.1	37.2	37.9	37.5
	024	36.1	39.0	38.2	38.0	38.8
	025	36.4	39.2	38.7	38.8	38.4
	026	37.3	37.4	36.6	37.7	37.7
	027	37.4	37.7	38.3	37.6	37.4
	028	37.2	37.6	37.0	37.9	38.3
	029	37.4	37.9	37.5	37.5	38.5
	030	37.8	37.9	38.4	37.9	38.3
3	031	36.7	38.6	37.3	38.5	38.5
	032	35.8	38.4	37.1	37.8	38.0
	033	36.7	38.4	37.1	38.2	38.0
	034	36.2	38.6	36.8	38.0	38.2
	035	37.0	38.5	38.1	38.8	39.1
	036	36.3	38.6	36.8	37.6	38.5
	037	37.4	38.8	37.1	37.6	38.5
	038	36.2	38.4	37.8	37.8	38.6
	039	36.2	38.6	37.0	37.8	38.0
	040	38.1	38.4	38.8	38.5	39.0
	041	36.1	37.9	37.7	38.2	37.8
	042	36.9	37.0	38.7	38.1	38.4

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Body Temp(BT)-(°C)

Males

Group #	Animal #	Dosing Day: 8 Session: S2-4 HPD	Day: 9 Session: S3-24 HPD	Day: 15 Session: S1-Predose	Session: S2-4 HPD	Day: 16 Session: S3-24 HPD
3	043	36.9	38.4	37.4	38.5	38.7
	044	36.6	38.3	37.6	37.5	38.7
	045	36.2	38.0	37.7	37.2	37.9

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Females

Group #	Animal #	PID Day: 6 Session: S1-Predose	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 8 Session: S1-Predose
1	046	38.3	37.4	37.0	37.7	38.2
	047	37.1	37.8	38.6	37.3	37.7
	048	38.7	38.0	38.2	37.7	37.9
	049	38.0	36.8	37.8	38.0	37.7
	050	38.0	38.0	38.2	37.5	38.0
	051	37.5	38.6	38.7	38.2	38.3
	052	38.5	37.6	38.2	37.8	37.8
	053	37.8	37.5	38.8	38.0	37.9
	054	37.7	38.4	37.6	37.6	38.8
	055	36.8	37.2	38.5	37.9	37.9
	056	38.5	37.0	37.7	37.0	38.0
	057	37.8	37.8	38.0	37.0	37.6
	058	37.8	35.9	36.9	37.3	38.0
	059	36.5	37.9	37.7	36.7	37.5
	060	37.2	37.7	38.0	37.5	37.8
2	061	36.2	36.9	37.8	37.6	37.9
	062	37.4	38.3	38.5	38.1	37.6
	063	37.4	37.4	38.2	37.5	38.0
	064	36.9	36.4	39.4	36.6	37.9
	065	38.5	38.3	38.1	38.9	37.7
	066	36.6	38.2	37.9	37.1	38.1

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Females

Group #	Animal #	PID Day: 6 Session: S1-Predose	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 8 Session: S1-Predose
2	067	36.8	38.4	38.7	37.8	38.3
	068	38.1	37.7	38.7	37.3	38.0
	069	37.8	36.7	39.0	39.0	37.7
	070	36.6	37.9	38.7	37.1	37.8
	071	37.3	37.1	37.1	37.8	37.6
	072	36.3	36.6	37.8	37.9	37.8
	073	38.1	37.4	39.3	38.2	38.2
	074	37.3	36.4	38.1	37.5	37.9
	075	36.6	38.3	38.6	38.0	37.5
3	076	38.5	37.9	38.7	38.2	37.7
	077	37.7	36.9	38.8	38.0	38.0
	078	37.6	38.3	38.6	38.1	37.9
	079	37.6	38.0	37.6	38.1	37.9
	080	38.1	38.8	38.5	37.7	38.0
	081	38.0	36.6	38.5	37.8	37.8
	082	38.8	37.6	39.0	38.7	37.7
	083	37.4	37.9	38.1	37.5	38.1
	084	36.5	38.2	39.1	38.4	37.7
	085	38.2	37.6	38.9	37.9	37.6
	086	38.6	37.6	37.9	37.9	38.0
	087	36.8	38.0	39.0	38.9	39.0

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Females

Group #	Animal #	PID Day: 6 Session: S1-Predose	Dosing Day: 1 Session: S1-Predose	Session: S2-4 HPD	Day: 2 Session: S3-24 HPD	Day: 8 Session: S1-Predose
3	088	38.6	38.8	38.7	37.8	37.9
	089	38.0	38.6	38.5	37.9	37.9
	090	36.1	37.9	38.3	37.9	38.1

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Females

Group #	Animal #	Dosing Day: 8 Session: S2-4 HPD	Day: 9 Session: S3-24 HPD	Day: 15 Session: S1-Predose	Session: S2-4 HPD	Day: 16 Session: S3-24 HPD
1	046	37.4	37.1	36.8	36.8	37.0
	047	38.0	37.0	37.3	37.0	37.7
	048	37.3	36.6	37.5	37.7	37.0
	049	37.0	37.8	37.0	37.8	37.7
	050	37.3	37.3	37.3	37.1	36.8
	051	37.9	38.3	37.1	39.0	37.3
	052	37.5	37.5	37.8	37.8	36.9
	053	38.0	37.7	37.1	38.3	37.1
	054	37.7	37.9	36.9	39.0	37.3
	055	37.7	37.4	37.2	36.5	36.7
	056	37.9	37.1	37.0	38.3	37.4
	057	38.7	37.1	37.3	39.1	37.5
	058	37.7	36.8	37.7	38.4	37.0
	059	36.9	38.0	37.2	38.5	37.5
	060	37.1	37.7	36.9	37.9	37.1
2	061	37.2	38.2	38.0	37.5	37.7
	062	38.0	38.6	38.1	38.9	37.7
	063	37.8	37.4	37.5	38.5	38.1
	064	37.8	37.9	38.1	39.2	37.6
	065	37.6	37.9	38.3	37.8	37.7
	066	37.5	38.5	37.1	37.6	37.0

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Test Article: BNT162b2(V9), BNT162b3c

Rat/Wistar Han

Repeat Dose Toxicity/Toxicity with Recovery

Body Temp(BT)-(°C)

Females

Group #	Animal #	Dosing Day: 8 Session: S2-4 HPD	Day: 9 Session: S3-24 HPD	Day: 15 Session: S1-Predose	Session: S2-4 HPD	Day: 16 Session: S3-24 HPD
2	067	37.6	38.9	38.3	38.8	37.9
	068	37.5	38.6	37.7	37.2	37.8
	069	39.2	38.1	37.5	38.2	37.8
	070	38.5	38.9	38.3	38.0	38.5
	071	37.8	38.5	37.8	37.3	37.3
	072	37.9	38.9	37.9	37.7	37.6
	073	37.9	37.8	38.1	38.1	37.4
	074	37.4	38.7	38.5	37.8	37.6
	075	37.9	38.5	38.7	38.3	37.7
3	076	38.1	38.9	38.2	38.3	37.0
	077	39.0	38.0	38.1	37.5	38.0
	078	38.3	38.9	37.7	38.5	37.9
	079	38.7	38.5	38.4	37.2	38.1
	080	37.7	38.9	37.8	37.0	38.3
	081	38.3	38.0	37.8	37.9	37.9
	082	38.1	39.3	38.3	38.6	38.2
	083	38.2	38.9	38.0	37.0	37.9
	084	37.8	38.5	37.9	38.4	37.8
	085	38.1	38.8	38.0	38.6	37.3
	086	38.4	38.9	37.7	38.6	37.8
	087	39.4	38.9	38.0	38.7	37.9

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Body Temperature Report with Individual Values

Printed: 23 Jul 2020 04:35:42 PM

Pfizer

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Study: 20GR142

StudyTitle: 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

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Body Temp(BT)-(°C)

Females

Group #	Animal #	Dosing Day: 8 Session: S2-4 HPD	Day: 9 Session: S3-24 HPD	Day: 15 Session: S1-Predose	Session: S2-4 HPD	Day: 16 Session: S3-24 HPD
3	088	38.0	38.0	38.2	38.8	37.7
	089	38.2	38.1	37.9	38.3	38.6
	090	37.9	38.3	38.1	38.0	37.2

S = Scheduled Animal Room, U = UnScheduled Animal Room, N = Scheduled Necropsy, n = UnScheduled Necropsy

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Ophthalmology Report for Study 20GR142

C O N F I D E N T I A L

OPHTHALMOLOGY REPORT:

17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Testing Facility Study Number: 20GR142

Alternative Test Article Identifier(s):

PF-07302048: Generic number for COVID-19 vaccine program

BNT162b2 (V9): BNT162b2 (Version 9); RBP020.2; PF-07305885

BNT162b3c: BNT162b3; RBP020.8; PF-07315256

TESTING FACILITY:
Pfizer
Drug Safety Research & Development
Eastern Point Road
Groton, CT 06340 USA

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Ophthalmology Report for Study 20GR142

SIGNATURES

I confirm that this report accurately reflects my interpretation of the ophthalmology data.

s 22

Clinical Veterinarian
Ophthalmology

For signatures see the Document Approval Record.

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Ophthalmology Report for Study 20GR142

GLP COMPLIANCE STATEMENT

This portion of the study was conducted in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies regulations as set forth in the Code of Federal Regulations (21 CFR Part 58).

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Ophthalmology Report for Study 20GR142

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Ophthalmology Report for Study 20GR142

1. INTRODUCTION AND OBJECTIVE

BNT162b2 (Version 9 [V9]) and BNT162b3c are candidate COVID-19 vaccines, which are based on an RNA platform and express the SARS-CoV-2 spike protein or its derivatives. The objective of this study was to determine the toxicity and development of a specific immune response to the antigens in each of the vaccine candidates following administration of intramuscular (IM) doses once weekly for a total of 3 doses to Wistar Han (Crl:WI[Han]) rats. The reversibility of effects was evaluated following a 3-week recovery phase.

Group designations and doses are indicated in the table below.

Group Number	Test Article or Vehicle Dose (µg RNA)/Dose Day	Dose Volume (µL/injection site)[a]	Animal Numbers	
			Males	Females
1	0[b]	60	1-15	46-60
2	30[c]	60	16-30	61-75
3	30[d]	60	31-45	76-90

a. Each animal received a single intramuscular injection on each dose day.
b. Sterile saline.
c. BNT162b2 (V9).
d. BNT162b3c.

Doses were administered by a single intramuscular injection (60 µL) on each dosing day (Days 1, 8, and 15) into the left hindlimb quadriceps muscle.

The first 10 animals/sex/group, by ascending animal order, were designated for necropsy at the end of the dosing phase. The remaining animals were retained for the recovery phase.

2. MATERIALS AND METHODS

Ophthalmic examinations were performed on animals (Groups 1-3) prior to the initiation of dosing (PID) on PID Day 7 for males and PID Day 8 for females, except for Animal 88 examined on PID Day 9, and on Day 15 for males and Day 16 for females. Tropicamide 1% was administered topically to each eye to facilitate the examination. Indirect ophthalmoscopy was used for examinations. Handheld slit lamp biomicroscopy was also used at the discretion of the examiner.

3. DATA ACQUISITION

Pristima Preclinical Data Management Suite (Version 7.4.3) was used to record ophthalmology data.

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4. DATA MANAGEMENT AND ARCHIVES

All raw data and the original report pertaining to this phase of the study are retained at Pfizer, DSRD, Groton, CT (USA). A copy of this report is appended to the study report.

Materials including raw data and documents electronically archived are retained in the Pfizer OpenLab archive system or locked and retained in the source computerized system, as defined per SOP.

5. RESULTS

An incidence summary of ophthalmic findings is presented in Table 2. Individual animal ophthalmic findings are included in Appendix 3.

Ophthalmic examinations of rats performed prior to initiation of dosing were within normal limits, except for incidental findings noted in the following animals: mild unilateral vitreous hemorrhage in Animal 8, minimal unilateral tortuous retinal vessels in Animal 10, minimal unilateral vitreous hyaloid remnant in Animal 11, and mild unilateral keratic precipitates in Animal 14 and Animal 41.

No test article-related ophthalmic findings were observed in rats at the end of the dosing phase.

The mild unilateral keratic precipitates observed on Day 16 in Animal 49 is a recognized spontaneous finding in Wistar Han rats and was not considered test article related (Williams, 2013). The Day 15 ophthalmic findings in Animals 8, 10, 11, 14, and 41 were consistent with those observed on PID Day 7.

Ophthalmic examinations were not conducted during the recovery phase due to the lack of test article-related changes at the end of the dosing phase.

6. INTEGRATED SUMMARY AND DISCUSSION OF RESULTS

Clinical ophthalmic parameters of rats examined in this study were not affected following 3 intramuscular doses of BNT162b2 (V9) or BNT162b3c administered 1 week apart.

7. REFERENCES

Williams, DL. Laboratory animal ophthalmology. In: Gelatt KN, Gilger BC, Kern TJ, eds. Veterinary Ophthalmology. 5th ed. Vol 2. Ames, IA: Wiley-Blackwell; 2013:1698.

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Document Approval Record

Document Name:	DSRD Ophthalmology Report
Document Title:	20GR142: DSRD Ophthalmology Report

Signed By:	Date(GMT)	Signing Capacity
S 22	04-Nov-2020 18:45:48	Author Approval

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VISMEDERI

Phase Report
20GR142 (Work Order 4)
Version 1.0 of 29 Oct 2020

PHASE REPORT

17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

20GR142 (WORK ORDER 4)

SERVICE PERFORMED BY:
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SPONSOR:
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Drug Safety Research & Development
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Groton, CT 06340 USA

Study Director
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Version summary:

VERSION	ISSUE DATE	CHANGE
0.1	24 Sept 2020	Draft report
0.2	05 Oct 2020	Sponsor review and data table added in Appendix
0.3	07 Oct 2020	Typo edits, margins and data table adaptation
1.0	29 Oct 2020	Final report

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ANALYSES FOR LIFE IMPROVEMENT

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VISMEDERI

1. PURPOSE

This Phase Report describes the activities completed by VisMederi applying the Microneutralization (MN) assay for serological detection of SARS-CoV-2 specific neutralizing antibodies in animal sera relative to the "Work order 4" agreed between VisMederi Srl and Pfizer.

2. STUDY MANAGEMENT

The BNT162b2 (V9) and BNT162b3c candidate COVID-19 vaccines, based on an RNA platform and target the SARS-CoV-2 spike protein, were evaluated through the 20GR142 study for toxicity and immune response development.

BNT162b2 (V9) and BNT162b3c were administered by intramuscular (IM) doses once weekly for a total of 3 doses to male and female Wistar Han (Crl:WI[Han]) rats. Animals received the vehicle or test article at doses of 30 µg RNA/Dose Day followed by a 3-week recovery phase. Group designations and doses are indicated in the table below.

Experimental Design				
Group Number	**Test Article or Vehicle Dose/Dose Day (µg/Dose Day)**	**Dose Volume (µL/injection site)[a]**	**Animal Numbers**	
			Males	**Females**
1	0[b]	60	1-15	46-60
2	30[c]	60	16-30	61-75
3	30[d]	60	31-45	76-90

a. Each animal received a single injection on each dose day.
b. Sterile saline
c. BNT162b2(V9)
d. BNT162b3c

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Doses were administered by a single intramuscular injection on each dosing day (60 µL) administered into the left hindlimb quadriceps muscle on Days 1, 8, and 15.

The first 10 animals/sex/group, by ascending animal order, were designated for necropsy at the end of the dosing phase. The remaining animals were retained for the recovery phase.

Samples for antibody response to the vaccine components were collected prior to dose initiation (PID) on PID Day 8 (Day -5), during the dosing phase on Day 17, and during the recovery phase (RP) on RP Day 21 (Day 38).

VisMederi performed immunogenicity tests on rats samples, testing for detection of neutralizing antibody titers to wild type live Sars-CoV-2 virus.
The assay was performed according to VisMederi internal working instruction "Microneutralization CPE-based assay for SARS-COV-2" (WI-MNSARS-CoV-2), in accordance with the Good Clinical Laboratory Practice 2009/2013 (GCLP).

VisMederi received, on August 24th 2020, 210 rat's serum samples, from Pfizer DSRD – Eastern Point Road, Groton, CT 06340, USA, for study 20GR142 with BNT162b2 (V9) and BNT162b3c. In particular, the shipment contained prior to initiation of dosing (PID) Day 8 (Day -5) and dosing phase Day 17 time-points samples of 90 animals and recovery phase (RP) Day 21 (Day 38) time-points from 30 rats.

Upon arrival, all samples passed a visual check of the physical characteristics and correspondence with material shipping inventory, according to the SOP-HBM of VisMederi, and they were stored in a freezer at -20°C (VM-F-009).

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Each serum sample of study 20GR142 has been tested in duplicate for serological detection of SARS-CoV-2 specific neutralizing antibodies.
The SARS-CoV-2 2019 live wild type virus 2019-nCoV strain 2019-nCov/Italy-INMI1 was obtained by VisMederi Srl from the European Virus Archive Global (EVAg).
The strain information are available at the following link:
https://www.european-virus-archive.com/virus/human-2019-ncov-strain-2019-ncovitaly-inmi1

The virus growth was carried out by VisMederi Research Srl, according to VisMederi Research procedure "Virus Growth in cell culture" (SOP-VGC) in epithelial cell line, VERO E6 cells (from kidney of a normal monkey Cercopithecus aethiops) provided by the American Type Culture Collection (ATCC - CRL 1586).

The internal virus batch applied for MN analyses was VMR_SARSCOV2VEROE6_280420_C1.
The Microneutralization assay for SARS-CoV-2 on rat sera samples were performed on 8th – 11th September 2020 in the VisMederi BSL3 laboratories in accordance to the SOP-HSAL of VisMederi.

QA Statement and Regulatory Statement

The work was conducted in accordance with the procedures in force and following the GCLP guidelines and under ISO 9001:2015.
All the laboratory staff involved was trained in recording the raw data of the study in a timely and accurate manner, and aware of the responsibility of the quality of the data produced.
Independent laboratory audits are conducted periodically to ensure the quality of work and data integrity.
Equipment used are periodically maintained, calibrated and qualified as appropriate.

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All the documentation related to the study is archived in a secure place in compliance with the ISO 27001 (both in electronic and paper format).
No significant laboratory events or deviations have occurred during the study that could have impacted the generated results.

3. TEST PROCEDURE

The MN-CPE (Microneutralization based on Cytopathic effect) method is a specific technique used for the identification of virus-specific neutralizing antibodies against live viruses which are able to prevent the virus infection. This assay is a fundamental test in virology, immunology, vaccine assessment and epidemiology studies.

The assay was performed following the VisMederi procedure "WI-MNSARS-CoV-2", and the main phases are described as follows:

- Virus Titration
- Back titration
- Microneutralization

Virus titration

The virus, ten-fold serially diluted in suitable MN medium, was transferred to a plate containing confluent VERO E6 cell monolayers.
After incubation of 3 days the plate was observed under an inverted microscope and the wells were scored as positive/negative for Cytopathic effect (CPE).
The titer was calculated using the Reed-Muench method, obtaining $10^{7.59}$ TCID50/mL as result. The stock virus was then applied in the MN assay at a proper dilution in order to contain 2000TCID50/mL in the working virus solution.

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MN assay

Serum samples were heat inactivated for 30 minutes at 56°C, then two-fold serially diluted starting from 1:10 up to 1:5120 and were mixed with an equal volume of viral solution.

Duplicate runs for each sample were performed in two different plates.

The serum-virus mixture was incubated for 1 hour at 37°C, in a humidified atmosphere with 5% CO_2. After the incubation time, 100 µl of the mixture for each dilution was added in duplicate to a cell plate containing a healthy and sub confluent-to confluent VERO E6 cell lawn and incubated for 3 days in the CO_2 incubator at 37°C and 5% CO_2. The readout was achieved through inverted optical microscopy in order to discriminate wells as positive/negative for Cytopathic effect (CPE).

The Microneutralization titer (MNt) of each titrated sample corresponded to the reciprocal of the highest sample dilution able to protect from CPE at least 50% of the cell monolayer. If no neutralization was observed (MNt <10) an arbitrary value of 5 was reported.

Back titration and reference samples

To verify the virus workload in the solution applied in the assay, the virus working solution was titrated in each MN session. The back titrations performed in both sessions for this study confirmed virus titers within the defined acceptance range of s 47

In addition, each test session included runs of specific reference sera: a positive and a negative serum.

The positive control (PCS) used in every test run, is a human plasma sample collected from a COVID-19 convalescent patient. The sample code TLS-8 was previously tested

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Document 2

by MN and by ELISA for SARS-CoV-2 antibody titer, providing high positive response confirmed by multiple repetitions.
The negative control sample (NCS) used was a human serum depleted of IgA, IgM and IgG, provided by Sigma Aldrich, cod. S5393 batch 108M4791V.

4. ACCEPTANCE CRITERIA

In agreement with WI-MNSARS-CoV-2, the following internal quality controls have been satisfied in each session of analysis for the Study 20GR142 samples, therefore results were considered reliable and acceptable.

Virus titer evaluation:

- The back titration of the working viral solution lies within the defined target range of s 47

MN results acceptability of each MN plate:

- The cell control (CC) showed a healthy cell monolayer and no evidence of CPE
- The virus control (VC) wells showed cytopathic effect.

MN results acceptability of each sample:

- The duplicate neutralization titers of each serum sample were within a range of s 47

MN results acceptability of each analysis session:

- the positive control sample (PCS) showed a positive titer, in agreement with previous data,
- the negative control sample (NCS) with absent antibody titer showed a negative response.

Since all the acceptability criteria were met, no retest was necessary.

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5. DATA RELEASE

Test results were recorded through dedicated forms, attachments of the VisMederi WI "WI-MNSARS-CoV-2", and transferred in an excel data entry sheet: PFZ_20GR142-WO4_MN-SarsCov2_V2_20200924_GL.xlsx

This report shows the full set of data in Appendix 1 and 2 tables.

Data entry description

The data tables present three sections:

- Sample identification
- Raw Data
- Derived values as geometric mean of duplicate tests

Each subject is identified in a row of table by Sample ID, gender and administered dose of vaccine. Any Study day is showed in following columns as duplicate results "T1A" and "T1B", each one is used for a replicate titer of the same sample. Last columns shows the geometric mean calculated from the two replicate titers for each study visit.

The following table shows geometric mean titers for grouped subjects by sex and for vaccine administered.

Table 1: Overview of GMTs for each dose group, by sampling day and sex

Study Day	Sex	Saline	30µg BNT162b2(V9)	30µg BNT162b3c
PID Day 8 (Day -5)	Male	5	5	5
	Female	5	5	5
Day 17	Male	5	1114	993
	Female	5	2501	1810
RP Day 21 (Day 38)	Male	5	5120	3880
	Female	5	5120	3880
PID = prior to dose initiation; RP = Recovery Phase				

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Administration of 3 once weekly doses of BNT162b2 (V9) or BNT162b3c elicited SARS-CoV-2 neutralizing antibody responses in males and females at the end of the dosing (Day 17) and recovery phases (Day 21) of the study. SARS-CoV-2 neutralizing antibody responses were not observed in animals prior to vaccine administration or in saline-administered control animals.

6. REFERENCES

- Manenti A, Maggetti M, Casa E, et al (2020). Evaluation of SARS-CoV-2 neutralizing antibodies using of a CPE-based Colorimetric live virus micro-neutralization assay in human serum samples. Journal of Medical Virology. doi: 10.1002/jmv.25986.
- Reed, L.J.; Muench, H. (1938). "A simple method of estimating fifty percent endpoints". The American Journal of Hygiene. 27: 493–497.
- Algaissi A, Hashem AM. (2020). Evaluation of MERS-CoV Neutralizing Antibodies in Sera Using Live Virus Microneutralization Assay. Methods in molecular biology (Clifton, N.J.) vol. 2099: 107-116.
- Good Clinical Laboratory Practice GCLP – 2009/2013
- OECD Principles on Good Laboratory Practice (ENV/MC/CHEM(98)17)
- UNI EN ISO 9001:2015
- UNI EN ISO 27001:2017
- "WI-MNSARS-CoV-2" Working Instruction "Microneutralization CPE-based assay for Sars-Cov-2"
- "HSAL" Handling and safety for activities in BSL2 and BSL3 Laboratories – VisMederi procedure
- "HBM" Handling Of Biological Material – Vismederi procedure
- "HCC" Handling Cell Cultures – VisMederi Research procedure
- "MRR" Management and Release of Results – VisMederi procedure
- "VGC" Virus Growth in Cell culture – VisMederi Research procedure

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7. APPENDICES

Appendix 1: data table for Male

Sample ID	Gender	Dose	Dose Units	T1A-DAY8	T1A-DAY17	T1A-DAY21	T1B-DAY8	T1B-DAY17	T1B-DAY21	Geometric Mean Day8	Geometric Mean Day17	Geometric Mean Day21
001M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
002M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
003M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
004M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
005M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
006M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
007M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
008M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
009M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
010M	Male	0	µg/kg	5	5		5	5		5.0	5.0	
011M	Male	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
012M	Male	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
013M	Male	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
014M	Male	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
015M	Male	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
016M	Male	30	µg/kg	5	2560		5	2560		5.0	2560.0	
017M	Male	30	µg/kg	5	640		5	640		5.0	640.0	
018M	Male	30	µg/kg	5	2560		5	1280		5.0	1810.2	
019M	Male	30	µg/kg	5	2560		5	2560		5.0	2560.0	
020M	Male	30	µg/kg	5	320		5	640		5.0	452.5	
021M	Male	30	µg/kg	5	2560		5	2560		5.0	2560.0	
022M	Male	30	µg/kg	5	640		5	1280		5.0	905.1	
023M	Male	30	µg/kg	5	1280		5	1280		5.0	1280.0	
024M	Male	30	µg/kg	5	1280		5	1280		5.0	1280.0	
025M	Male	30	µg/kg	5	1280		5	1280		5.0	1280.0	
026M	Male	30	µg/kg	5	320	5120	5	320	5120	5.0	320.0	5120.0
027M	Male	30	µg/kg	5	640	5120	5	320	5120	5.0	452.5	5120.0
028M	Male	30	µg/kg	5	1280	5120	5	1280	5120	5.0	1280.0	5120.0
029M	Male	30	µg/kg	5	320	5120	5	640	5120	5.0	452.5	5120.0
030M	Male	30	µg/kg	5	2560	5120	5	5120	5120	5.0	3620.4	5120.0
031M	Male	30	µg/kg	5	2560		5	2560		5.0	2560.0	
032M	Male	30	µg/kg	5	320		5	320		5.0	320.0	
033M	Male	30	µg/kg	5	2560		5	2560		5.0	2560.0	
034M	Male	30	µg/kg	5	1280		5	2560		5.0	1810.2	
035M	Male	30	µg/kg	5	160		5	160		5.0	160.0	
036M	Male	30	µg/kg	5	640		5	640		5.0	640.0	
037M	Male	30	µg/kg	5	160		5	320		5.0	226.3	
038M	Male	30	µg/kg	5	1280		5	1280		5.0	1280.0	
039M	Male	30	µg/kg	5	320		5	320		5.0	320.0	
040M	Male	30	µg/kg	5	2560		5	2560		5.0	2560.0	
041M	Male	30	µg/kg	5	2560	5120	5	5120	5120	5.0	3620.4	5120.0
042M	Male	30	µg/kg	5	1280	5120	5	1280	5120	5.0	1280.0	5120.0
043M	Male	30	µg/kg	5	2560	5120	5	2560	5120	5.0	2560.0	5120.0
044M	Male	30	µg/kg	5	640	2560	5	640	2560	5.0	640.0	2560.0
045M	Male	30	µg/kg	5	1280	2560	5	1280	2560	5.0	1280.0	2560.0

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Appendix 2: data table for Female

Sample ID	Gender	Dose	Dose Units	T1A-DAY8	T1A-DAY17	T1A-DAY21	T1B-DAY8	T1B-DAY17	T1B-DAY21	Geometric Mean Day8	Geometric Mean Day17	Geometric Mean Day21
046F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
047F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
048F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
049F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
050F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
051F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
052F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
053F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
054F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
055F	Female	0	µg/kg	5	5		5	5		5.0	5.0	
056F	Female	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
057F	Female	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
058F	Female	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
059F	Female	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
060F	Female	0	µg/kg	5	5	5	5	5	5	5.0	5.0	5.0
061F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
062F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
063F	Female	30	µg/kg	5	640		5	640		5.0	640.0	
064F	Female	30	µg/kg	5	2560		5	2560		5.0	2560.0	
065F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
066F	Female	30	µg/kg	5	2560		5	2560		5.0	2560.0	
067F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
068F	Female	30	µg/kg	5	2560		5	2560		5.0	2560.0	
069F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
070F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
071F	Female	30	µg/kg	5	2560	5120	5	2560	5120	5.0	2560.0	5120.0
072F	Female	30	µg/kg	5	2560	5120	5	5120	5120	5.0	3620.4	5120.0
073F	Female	30	µg/kg	5	5120	5120	5	5120	5120	5.0	5120.0	5120.0
074F	Female	30	µg/kg	5	1280	5120	5	1280	5120	5.0	1280.0	5120.0
075F	Female	30	µg/kg	5	1280	5120	5	1280	5120	5.0	1280.0	5120.0
076F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
077F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
078F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
079F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
080F	Female	30	µg/kg	5	640		5	640		5.0	640.0	
081F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
082F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
083F	Female	30	µg/kg	5	1280		5	1280		5.0	1280.0	
084F	Female	30	µg/kg	5	5120		5	5120		5.0	5120.0	
085F	Female	30	µg/kg	5	2560		5	2560		5.0	2560.0	
086F	Female	30	µg/kg	5	320	1280	5	320	1280	5.0	320.0	1280.0
087F	Female	30	µg/kg	5	5120	5120	5	5120	5120	5.0	5120.0	5120.0
088F	Female	30	µg/kg	5	1280	5120	5	2560	5120	5.0	1810.2	5120.0
089F	Female	30	µg/kg	5	640	5120	5	640	5120	5.0	640.0	5120.0
090F	Female	30	µg/kg	5	5120	5120	5	5120	5120	5.0	5120.0	5120.0

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Clinical Pathology Report for Study 20GR142

C O N F I D E N T I A L

CLINICAL PATHOLOGY REPORT: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Testing Facility Study Number: 20GR142

Alternative Test Article Identifier(s):

PF-07302048: Generic number for COVID-19 vaccine program

BNT162b2 (V9): BNT162b2 (Version 9); RBP020.2; PF-07305885

BNT162b3c: BNT162b3; RBP020.8; PF-07315256

TESTING FACILITY
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Clinical Pathology Report for Study 20GR142

SIGNATURES

I was responsible for the principal investigator activities conducted in support of this study and confirm that this report accurately reflects my interpretation of the clinical pathology data and that my portions of the study were conducted in compliance with GLP regulations with the exceptions noted; (see GLP Compliance Statement).

[redacted] s 22

Clinical Pathologist
Principal Investigator

Quality Assurance Statement Signature

The signature for the following individual applies only to the Pearl River, NY Quality Assurance Statement contained in this study report.

[redacted] s 22 , Pfizer Inc, Pearl River, NY.

For signatures see the Document Approval Record located on the last page of this report.

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GLP COMPLIANCE STATEMENT

This portion of the study was conducted in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies regulations as set forth in the Code of Federal Regulations (21 CFR Part 58) with the exception of the analyses of alpha-1 acid glycoprotein (A1AGP) and alpha-2-macroglobulin (A2M) which were conducted under non-GLP conditions, but according to fit-for-purpose methods. This exception did not have an impact on the integrity or data interpretation of the study.

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1. INTRODUCTION

BNT162b2 (Version 9 [V9]) and BNT162b3c are candidate COVID-19 vaccines, which consist of an LNP-encapsulated RNA encoding the SARS-CoV-2 spike protein or its derivatives, were administered by intramuscular (IM) doses once weekly for a total of 3 doses to male and female Wistar Han (Crl:WI[Han]) rats. Animals received the vehicle or test article at doses of 0 or 30 µg RNA/Dose Day followed by a 3-week recovery phase. Group designations and doses are indicated in the table below.

Experimental Design				
Group Number	**Test Article or Vehicle Dose (µg RNA/Dose Day)**	**Dose Volume (µL/injection site)[a]**	**Animal Numbers**	
			Males	**Females**
1	0[b]	60	1-15	46-60
2	30[c]	60	16-30	61-75
3	30[d]	60	31-45	76-90

a. Each animal received a single injection on each dose day.
b. Sterile saline.
c. BNT162b2 (V9).
d. BNT162b3c.

Doses were administered by a single intramuscular injection on each dosing day (60 µL) administered into the left hindlimb quadriceps muscle on Days 1, 8, and 15.

The first 10 animals/sex/group, by ascending animal order, were designated for necropsy at the end of the dosing phase. The remaining animals were retained for the recovery phase.

2. MATERIALS AND METHODS

Clinical laboratory measurements were completed at the Testing Facility (Pfizer DSRD, Groton, CT) and clinical laboratory measurements interpretation was completed at the Test Site (Pfizer DSRD, Pearl River, NY).

2.1. Clinical Laboratory Measurements

Clinical laboratory parameters were evaluated in samples collected from all animals as listed in each section below.

Bone marrow smears were prepared for all animals. Bone marrow smear slides were stained with May-Grunwald Giemsa and were not examined.

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Schedule for Collection of Samples for Clinical Laboratory Measurements			
Parameter	**Day of Study**		
	Dosing Phase		**Recovery Phase**
	Day 4	Day 17[e]	Day 22
Hematology	X[a,c]	X[c]	X[c]
Coagulation	NA	X[c]	X[c]
Clinical Chemistry (Core Chemistry)	X[b,c]	X[c]	X[c]
Clinical Chemistry (Other Biomarkers – Acute Phase Proteins)/Serum[d]	X[b,c]	X[c]	X[c]
Urinalysis	NA	X	X

NA = Not applicable; X = Scheduled Collection.
a. First 7 animals/sex/group.
b. Last 8 animals/sex/group.
c. Blood samples were collected from animals in a fasted state, with the exception of same day redraws.
d. Assay performed using shared clinical chemistry sample.
e. Evaluated on animals scheduled for necropsy.

Blood Collection			
Parameter	**Collection Condition**	**Approximate Blood Volume**	**Anticoagulant**
Clinical Chemistry	Nonterminal[a, b]	0.7 mL	None-Serum Separator Tube
Clinical Chemistry	Terminal	2.5 mL	None-Serum Separator Tube
Hematology	Nonterminal[a,b]	0.5 mL	K_2EDTA
Hematology	Terminal	2.0 mL	K_2EDTA
Coagulation	Terminal	2.0 mL	3.2% sodium citrate
Biomarkers (Clinical Chemistry)	Nonterminal[a,b]	using shared sample	None-Serum Separator Tube
Biomarkers (Clinical Chemistry)	Terminal	Using shared sample	None-Serum Separator Tube

a. Blood samples were collected under anesthesia.
b. This volume was based on collecting blood for one parameter per group of animals and the other parameter on another group of animals.

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2.1.1. Hematology and Coagulation

Blood samples were analyzed for:

Red Blood Cells (RBC)	Red Cell Distribution Width (RDW)
Hemoglobin (HGB)	Reticulocytes (RETIC)
Hematocrit (HCT)	Platelets (PLT)
Mean Cell Volume (MCV)	Mean Platelet Volume (MPV)
Mean Cell Hemoglobin (MCH)	White Blood Cells (WBC)
Mean Cell Hemoglobin Concentration (MCHC)	White Cell Differential

Blood smears were prepared for the first 7 animals on Day 4 and all animals on Dosing Phase Day 17 and Recovery Phase Day 21 (Groups 1-3).
Blood cell morphology was evaluated microscopically on 5 animals of each sex from all groups at both scheduled necropsies (ie, at dosing and recovery phases).

Blood samples were analyzed for:

Activated Partial Thromboplastin Time (APTT)	Prothrombin Time (PT_Rat)
Fibrinogen (FIB)	

2.1.2. Clinical Chemistry

Core Chemistry

Serum samples were analyzed for:

Alanine Aminotransferase (ALT)	Globulin (GLOB)
Aspartate Aminotransferase (AST)	Albumin/Globulin Ratio (AG)
Alkaline Phosphatase (ALP)	Blood Urea Nitrogen (BUN)
Gamma Glutamyltransferase (GGT)	Creatinine (CREA)
Bilirubin, Total (TBIL)	Phosphorus (PHOS)
Cholesterol (CHOL)	Calcium (CA)
Triglyceride (TRIG)	Sodium (NA)
Glucose (GLUC)	Potassium (K)
Total Protein (TP)	Chloride (CL)
Albumin (ALB)	

Serum indices for hemolysis, icterus, and lipemia were performed.

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Other Biomarkers

Serum Biomarker Sample Collection

Serum samples were analyzed for:

alpha-1-acid glycoprotein (A1AGP)	alpha-2-macroglobulin (A2M)

2.1.3. Urinalysis

Urine samples were collected overnight at scheduled necropsy. Urine samples were analyzed for:

Color	Protein (PRO)
Clarity	Blood
pH	Bilirubin (BIL)
Glucose Urine (GLU)	Specific Gravity (SG)
Ketones (KET)	Volume

Microscopic examination of sediment for formed elements was performed on 5 animals of each sex from all dose groups at both scheduled necropsies (ie, dosing and recovery phases).

2.2. Statistical Analysis

Statistical analyses of hematology, coagulation, clinical chemistry, and urinalysis data was conducted in Pristima. All analyses were performed separately for each sex.

Descriptive statistics were generated for each parameter and group at each scheduled sampling time or each time interval. Statistical tests were conducted at the 5% and 1% significance levels.

Analyses of hematology, coagulation, clinical chemistry, and urinalysis parameters were done on measurements collected for each animal at the scheduled sampling times or time intervals.

A nonparametric (rank-transform) one way analysis of variance (ANOVA) on all groups was conducted, with two-sided pairwise comparisons of Groups 2 and 3 to Group 1 using Dunnett's test. Average ranks were assigned to ties.

3. DATA ACQUISITION

Cerner HNA Millennium Laboratory Information System (Version 2018.01) was used to record clinical laboratory measurement data.

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4. DATA MANAGEMENT AND ARCHIVES

Raw data, documentation, protocol and amendments, final report, and any specimens generated at the Test Facility as the result of the study are retained at Pfizer, Groton, CT.

Materials including raw data and documents electronically archived are retained in the Pfizer OpenLab archive system or locked and retained in the source computerized system, as defined per SOP.

Materials are retained in accordance with the Enterprise Records Retention Schedule.

5. RESULTS

5.1. Clinical Laboratory Measurements

5.1.1. Hematology and Coagulation

Group mean hematology and coagulation data are presented in Table 6. Individual animal hematology and coagulation data are included in Appendix 7. Results indicated below are test article group mean values compared with control group mean values.

Dosing Phase

Test article-related hematology and coagulation findings were similar in rats administered either BNT162b2 (V9) or BNT162b3c and included higher mean white blood cell (WBC) counts and fibrinogen concentrations, lower (Day 4) and higher (Day 17) reticulocyte counts, and lower red blood cell mass (red blood cell [RBC] count, hemoglobin [HGB] and hematocrit [HCT], as represented by HCT in Text Table 1) compared with controls.

Higher WBC primarily involved neutrophils, monocytes and large unstained cells (LUC) but also affected eosinophils and basophils. They were present on Days 4 and 17, with higher counts on Day 17 than Day 4. On Day 17, there were also test article-related higher fibrinogen concentrations in both sexes. Hypersegmented neutrophils were present on peripheral blood smears of test article-treated animals.

In addition, there were test article-related transiently lower reticulocyte counts on Day 4, and higher reticulocytes on Day 17 (females only) with attendant expected changes in RBC indices (higher mean cell hemoglobin concentration [MCHC; males] on Day 4; lower mean cell hemoglobin [MCH] and higher red cell distribution width [RDW] on Day 17; both sexes). These were associated with lower RBC mass on Days 4 & 17 (comparable on both days or slightly lower on Day 17).

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Text Table 1. Test Article-Related Hematology and Coagulation Parameter Effects (Mean Control Values and Ratio Relative to Control Mean)

Dose (µg RNA/Dose Day)						
Parameter	Males			Females		
Test Article	Vehicle	BNT162b2(V9)	BNT162b3c	Vehicle	BNT162b2(V9)	BNT162b3c
	0	30	30	0	30	30
HCT (%)						
4D	48.04	0.90x	0.91x	44.91	0.93x	0.93x
17D	42.61	0.90x	0.92x	41.67	0.91x	0.89x
MCH (pg)						
4D	18.51	-	-	18.37	-	-
17D	18.27	0.96x	-	18.62	0.97x	0.96x
MCHC (g/dL)						
4D	31.24	1.04x	1.03x	32.34	-	-
17D	32.46	-	-	33.18	-	-
RDW (%)						
4D	12.27	-	-	11.11	-	-
17D	11.63	1.21x	1.18x	11.33	1.18x	1.18x
RETIC (10e3/uL)						
4D	392.1	0.27x	0.27x	301.7	0.43x	0.44x
17D	178.8	-	-	168.9	1.31x	1.20x
WBC (10e3/uL)						
4D	7.60	1.41x	1.28x	6.01	1.30x	1.43x
17D	3.84	2.30x	2.24x	2.16	2.64x	2.95x
NEUT (10e3/uL)						
4D	1.083	2.28x	2.00x	0.920	2.51x	3.13x
17D	0.674	6.60x	6.46x	0.409	6.04x	7.04x
MONO (10e3/uL)						
4D	0.109	1.83x	1.96x	0.093	1.89x	2.52x
17D	0.071	3.30x	3.58x	0.056	2.75x	3.14x
EO (10e3/uL)						
4D	0.081	-	-	0.057	-	2.16x
17D	0.056	2.52x	2.18x	0.029	3.17x	3.34x
BASO (10e3/uL)						
4D	0.016	1.88x	2.31x	0.009	1.89x	2.67x
17D	0.003	5.67x	6.33x	0.001	8.00x	10.00x
LUC (10e3/uL)						
4D	0.046	4.07x	3.98x	0.030	4.20x	4.43x
17D	0.026	8.04x	12.42x	0.010	13.20x	19.00x

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Text Table 1. Test Article-Related Hematology and Coagulation Parameter Effects (Mean Control Values and Ratio Relative to Control Mean) - Continued

Dose (µg RNA/Dose Day)						
Parameter	Males			Females		
Test Article	Vehicle	BNT162b2(V9)	BNT162b3c	Vehicle	BNT162b2(V9)	BNT162b3c
	0	30	30	0	30	30
FIB (mg/dL)						
17D	253.1	2.36x	2.39x	217.2	2.49x	2.59x

Control mean values and the ratio of the test article-related findings relative to control means are listed.
- = Not test article related; BASO = Basophil, absolute; D = Day; EO = Eosinophil, absolute; FIB = Fibrinogen; HCT = Hematocrit; LUC = Large unstained cells, absolute; MCH = Mean cell hemoglobin; MCHC = Mean cell hemoglobin concentration; MONO = Monocyte, absolute; NEUT = Neutrophil, absolute; RDW = Red cell distribution width; RETIC = Reticulocyte, absolute; WBC = White blood cells.

Recovery Phase

All test article related changes were fully reversed after a 3-week recovery period, with the exception of higher RDW (Text Table 2).

Text Table 2. Test Article-Related Hematology and Coagulation Parameter Effects (Mean Control Values and Ratio Relative to Control Mean)

Dose (µg RNA/Dose Day)						
Parameter	Males			Females		
Test Article	Vehicle	BNT162b2(V9)	BNT162b3c	Vehicle	BNT162b2(V9)	BNT162b3c
	0	30	30	0	30	30
RDW (%)						
R22	11.93	1.13x	1.12x	10.80	1.21x	1.23x

Control mean values and the ratio of the test article-related findings relative to control means are listed.
R = Recovery Day; RDW = Red cell distribution width.

Other statistically significant or apparent differences between test article and control group hematology and coagulation parameters were not test article related due to one or more of the following: small magnitude of the difference, inconsistent direction of the difference, and general overlap in magnitude of individual values with controls.

5.1.2. Clinical Chemistry

Group mean clinical chemistry data are presented in Table 7. Individual animal clinical chemistry data are included in Appendix 8. Results indicated below are test article group mean values compared with control group mean values.

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Dosing Phase

Test article-related clinical chemistry findings were similar in rats administered 30 µg RNA/dosing day of either BNT162b2 (V9) or BNT162b3c and included higher mean alpha-1 acid glycoprotein (A1AGP) and alpha-2-macroglobulin (A2M) and lower albumin:globulin (AG) ratios (primarily due to lower albumin with slight contribution from higher globulins) on Days 4 and 17 in both sexes compared with controls (Text Table 3).

Text Table 3. Test Article-Related Clinical Chemistry Parameter Effects (Mean Control Values and Ratio Relative to Control Mean)

Dose (µg RNA/Dose Day)						
Parameter	Males			Females		
Test Article	Vehicle	BNT162b2(V9)	BNT162b3c	Vehicle	BNT162b2(V9)	BNT162b3c
	0	30	30	0	30	30
ALB (g/dL)						
4D	3.98	0.93x	0.92x	4.16	0.86x	0.90x
17D	3.50	-	-	3.60	0.85x	0.86x
GLOB (g/dL)						
4D	2.13	-	-	2.10	-	1.05x
17D	1.89	1.10x	1.07x	1.84	1.04x	-
AG						
4D	1.88	0.90x	0.90x	1.98	0.86x	0.85x
17D	1.85	0.89x	0.89x	1.96	0.82x	0.85x
A1AGP						
4D	174.358	9.42x	13.49x	239.774	7.95x	6.99x
17D	47.672	38.51x	42.40x	95.959	15.55x	17.21x
A2M						
4D	113.4	20.44x	34.99x	212.1	3.32x	4.18x
17D	14.0	70.76x	128.16x	33.1	15.74x	17.89x

Control mean values and the ratio of the test article-related findings relative to control means are listed.
- = Not test article related; A1AGP = alpha-1 acid glycoprotein; A2M = alpha-2-macroglobulin; AG = Albumin/globulin ratio; ALB = Albumin; D = Day; GLOB = Globulin; TP = Protein, total.

Recovery Phase

All test article related changes were fully reversed after a 22-day recovery period, with the exception of higher globulins in males administered BNT162b2 (V9) and females administered BNT162b2 (V9) and BNT162b3c, and lower AG ratio in females administered BNT162b2 (V9) (see Text Table 4).

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Text Table 4. Test Article-Related Clinical Chemistry Parameter Effects (Mean Control Values and Ratio Relative to Control Mean)

Dose (µg RNA/Dose Day)						
Parameter	Males			Females		
Test Article	Vehicle	BNT162b2(V9)	BNT162b3c	Vehicle	BNT162b2(V9)	BNT162b3c
	0	30	30	0	30	30
GLOB (g/dL)						
R22	2.10	1.08x	-	2.26	1.06x	1.07x
AG						
R22	1.76	-	-	1.90	0.91x	-

Control mean values and the ratio of the test article-related findings relative to control means are listed.
- = Not test article related; AG = Albumin/globulin ratio; GLOB = Globulin; R = Recovery Day.

Other statistically significant or apparent differences between test article and control group clinical chemistry parameters were not test article related due small magnitude of the difference and general overlap in magnitude of individual values with controls.

5.1.3. Urinalysis

Group mean urinalysis data are presented in Table 8. Individual animal urinalysis data are included in Appendix 9.

Dosing and Recovery Phases

There were no test article-related findings on urinalysis.

All statistically significant or apparent differences in urinalysis parameters between test article and control group were not test article related due small magnitude of the difference and general overlap in magnitude of individual values with controls.

6. INTEGRATED SUMMARY AND DISCUSSION OF RESULTS

Male and female Wistar-Han rats were administered either BNT162b2 (V9) or BNT162b3c at 30 µg RNA/Dose Day by intramuscular (IM) injection once weekly for 3 weeks, resulting in nonadverse findings in hematology and clinical chemistry parameters compared with control animals.

All clinical pathology findings (type and magnitude) were generally comparable between rats administered BNT162b2 (V9) or BNT162b3c, and consistent with expected immune responses to vaccines or secondary to inflammation. The main findings were present in males and females on Days 4 and/or 17 and included higher acute phase proteins (alpha-1

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acid glycoprotein [A1AGP; 7.0x – 42x controls], alpha-2-macroglobulin [A2M; 3.3x – 128x] and fibrinogen [2.4x-2.6x]), lower albumin:globulin (AG; 0.90x - 0.82x; primarily due to lower albumin [0.93x – 0.85x] with slight contribution from globulins [1.04x – 1.10x]), and higher WBC (1.28x - 2.95x; primarily involving neutrophils, monocytes and LUC, which typically represent large mononuclear cells). Hypersegmented neutrophils present on peripheral blood smears were considered to be secondary to the robust increases in neutrophil counts and likely related to mobilization of bone marrow storage neutrophils and prolonged neutrophil lifespan in circulation (Ulich et al, 1988). Collectively, these findings were consistent with expected immune responses to vaccines. Microscopic correlates included minimally increased cellularity of hematopoietic cells (primarily myeloid) in the bone marrow and the spleen, minimal to moderate mixed cell inflammation at the injection site and increased cellularity in germinal centers of lymphoid organs.

In addition, there were transiently lower reticulocyte counts on Day 4 (0.44x - 0.27x), and higher reticulocytes on Day 17 (1.20x - 1.31x; females only), with minor lower red cell mass on Days 4 and 17 (HCT; 0.93x - 0.89x). Lower reticulocytes were interpreted to be a transient effect of innate immune responses (Abreu et al, 2018; Brooks et al, 2017; Kim et al, 2014; Wrighting & Andrews, 2006).

All test article related changes were fully reversed after a 3-week recovery period, with the exception of higher RDW in males and females administered BNT162b2 (V9) (1.13x and 1.21x, respectively) and BNT162b3c (1.12x and 1.23x, respectively), higher globulins in males administered BNT162b2 (V9) (1.08x) and females administered BNT162b2 (V9) (1.06x) and BNT162b3c (1.07x), and lower AG ratio in females administered BNT162b2 (V9) (0.91x).

In conclusion, clinical pathology findings in rats administered BNT162b2 (V9) or BNT162b3c were consistent with expected immune responses to vaccines or secondary to inflammation and included higher acute phase proteins (A1AGP, A2M and fibrinogen), higher WBC (primarily neutrophils, monocytes and LUC), lower red blood cell mass and transiently lower reticulocytes.

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Medical Quality Assurance

Quality Assurance Statement

Title: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study: 20GR142

In accordance with Pfizer policies and Medical Quality Assurance procedures for Good Laboratory Practice (GLP), the conduct of this portion of this study has been inspected and/or audited as follows.

Phase Inspected	Audit/Inspection Date GMT	Reporting Date GMT
Test Site Protocol Review	24-Jun-2020 to 25-Jun-2020	25-Jun-2020
Protocol Amendment #1	02-Jul-2020 to 02-Jul-2020	02-Jul-2020
Protocol Amendment #4	04-Sep-2020 to 04-Sep-2020	04-Sep-2020
Report: Clinical Pathology	20-Oct-2020 to 30-Oct-2020	03-Nov-2020
Report: Pathology	20-Oct-2020 to 30-Oct-2020	03-Nov-2020

In addition Routine Facility and Process audits are conducted in accordance with MQA SOPs and Site Monitoring Plans.

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Document Approval Record

Document Name:	Clinical Pathology Report
Document Title:	20GR142 Clinical Pathology Report

Signed By:	Date(GMT)	Signing Capacity
s 22	09-Nov-2020 21:24:21	Quality Assurance Approval
s 22	10-Nov-2020 20:16:43	Author Approval

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C O N F I D E N T I A L

ANATOMIC PATHOLOGY REPORT: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Testing Facility Study Number: 20GR142

Alternative Test Article Identifier(s):

PF-07302048: Generic number for COVID-19 vaccine program

BNT162b2 (V9): BNT162b2 (Version 9); RBP020.2; PF-07305885

BNT162b3c: BNT162b3; RBP020.8; PF-07315256

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Anatomic Pathology Report for Study 20GR142

SIGNATURES

I was responsible for the principal investigator activities conducted in support of this study and confirm that this report accurately reflects my interpretation of the organ weight, macroscopic, and microscopic data and that my portions of the study were conducted in compliance with GLP regulations (see GLP Compliance Statement).

[redacted]

Quality Assurance Statement Signature

The signature for the following individual applies only to the Pearl River, NY Quality Assurance Statement contained in this study report.

[redacted] Pfizer Inc, Pearl River, NY.

For signatures see the Document Approval Record located on the last page of this report.

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GLP COMPLIANCE STATEMENT

This portion of the study was conducted in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies regulations as set forth in the Code of Federal Regulations (21 CFR Part 58).

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OTHER STUDY PERSONNEL

The following study personnel were involved in the conduct of this study:

Peer Review Pathologist:	s 22 s 22

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PFIZER CONFIDENTIAL

Anatomic Pathology Report for Study 20GR142

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1. INTRODUCTION

BNT162b2 (Version 9 [V9]) and BNT162b3c are candidate COVID-19 vaccines, which consist of an LNP-encapsulated RNA encoding the SARS-CoV-2 spike protein or its derivatives, were administered intramuscularly (IM) once weekly for a total of 3 doses to male and female Wistar Han (Crl:WI[Han]) rats. Animals received the vehicle or test article at doses of 30 µg RNA/dosing day followed by a 3-week recovery phase. Group designations and doses are indicated in the table below.

Experimental Design				
Group Number	Test Article or Vehicle Dose (µg RNA/Dose Day)	Dose Volume (µL/injection site)[a]	Animal Numbers Males	Females
1	0[b]	60	1-15	46-60
2	30[c]	60	16-30	61-75
3	30[d]	60	31-45	76-90

a. Each animal received a single injection on each dose day.
b. Sterile saline.
c. BNT162b2(V9).
d. BNT162b3c.

Doses were administered by a single intramuscular injection (60 µL) on each dosing day (Days 1, 8, and 15) into the left hindlimb quadriceps muscle.

The first 10 animals/sex/group, by ascending animal order, were designated for necropsy at the end of the dosing phase (Day 17). The remaining animals were retained for the recovery phase.

2. MATERIALS AND METHODS

Necropsy, organ weights, macroscopic examination, tissue collection, tissue processing, and slide preparation were completed at the Testing Facility (Pfizer DSRD, Groton, CT) and microscopic examination and peer review were completed at the Test Site (Pfizer DSRD, Pearl River, NY).

2.1. Postmortem Observations

2.1.1. Euthanasia

Animals were euthanized by gas anesthesia (isoflurane) followed by exsanguination.

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2.1.2. Necropsy

2.1.2.1. Scheduled Necropsy

Animals from the dosing phase were fasted overnight and euthanized on Dosing Phase Day 17, 2 days after the last dose (first 10 animals/sex/group). Animals from the recovery phase were fasted overnight and euthanized on Recovery Phase Day 22 (remaining 5 animals/sex/group). Complete necropsies, tissue collection, organ weights, and macroscopic tissue evaluation were performed on all animals. Necropsy included macroscopic examination of the external surface of the body, the thoracic and abdominal cavities and their contents, and the collection of all protocol-defined tissues.

2.1.2.2. Tissue Collection, Organ Weights and Tissues Processed for Slide Preparation – Dosing Phase

Tissues Collected	Organs Weighed (All Dose Groups)	Tissues Processed for Slide Preparation (X) Dose Group		
		Group 1	Group 2	Group 3
Artery, Aorta		X	X	X
Bone Marrow, Sternum		X	X	X
Bone, Sternum		X	X	X
Brain	X	X	X	X
Cervix		X	X	X
Epididymis	X	X	X	X
Esophagus		X	X	X
Eye		X	X	X
Gland, Adrenal	X	X	X	X
Gland, Harderian		X	X	X
Gland, Lacrimal (Extraorbital)		X	X	X
Gland, Mammary		X	X	X
Gland, Parathyroid		X	X	X
Gland, Pituitary		X	X	X
Gland, Prostate	X	X	X	X
Gland, Salivary		X	X	X
Gland, Seminal Vesicle		X	X	X
Gland, Thyroid		X	X	X
Gut-Associated Lymphoid Tissue		X	X	X
Heart	X	X	X	X
Joint		X	X	X
Kidney	X	X	X	X
Large Intestine, Cecum		X	X	X
Large Intestine, Colon		X	X	X
Larynx				

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Tissues Collected	Organs Weighed (All Dose Groups)	Tissues Processed for Slide Preparation (X) Dose Group		
		Group 1	Group 2	Group 3
Liver	X	X	X	X
Lung		X	X	X
Lymph Node, Draining		X	X	X
Lymph Node, Inguinal		X	X	X
Lymph Node, Mesenteric		X	X	X
Macroscopic Findings		X	X	X
Muscle, Skeletal		X	X	X
Nerve, Optic		X	X	X
Nerve, Peripheral		X	X	X
Ovary	X	X	X	X
Oviduct		X	X	X
Pancreas		X	X	X
Site, Injection		X	X	X
Skin		X	X	X
Small Intestine, Duodenum		X	X	X
Small Intestine, Ileum		X	X	X
Small Intestine, Jejunum		X	X	X
Spinal Cord		X	X	X
Spleen	X	X	X	X
Stomach		X	X	X
Testis	X	X	X	X
Thymus	X	X	X	X
Tongue		X	X	X
Trachea		X	X	X
Ureter		X	X	X
Urinary Bladder		X	X	X
Uterus		X	X	X
Vagina		X	X	X

2.1.2.3. Tissue Collection, Organ Weights and Tissues Processed for Slide Preparation – Recovery Phase

Tissues Collected	Organs Weighed (All Dose Groups)	Tissues Processed for Slide Preparation (X) Dose Group		
		Group 1	Group 2	Group 3
Artery, Aorta				
Bone Marrow, Sternum		X	X	X
Bone, Sternum				
Brain	X			

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Tissues Collected	Organs Weighed (All Dose Groups)	Tissues Processed for Slide Preparation (X) Dose Group		
		Group 1	Group 2	Group 3
Cervix				
Epididymis	X			
Esophagus				
Eye				
Gland, Adrenal	X			
Gland, Harderian				
Gland, Lacrimal (Extraorbital)				
Gland, Mammary				
Gland, Parathyroid				
Gland, Pituitary				
Gland, Prostate	X			
Gland, Salivary				
Gland, Seminal Vesicle				
Gland, Thyroid				
Gut-Associated Lymphoid Tissue				
Heart	X			
Joint		X	X	X
Kidney	X			
Large Intestine, Cecum				
Large Intestine, Colon				
Larynx				
Liver	X	X	X	X
Lung				
Lymph Node, Draining		X	X	X
Lymph Node, Inguinal		X	X	X
Lymph Node, Mesenteric				
Macroscopic Findings		X	X	X
Muscle, Skeletal		X	X	X
Nerve, Optic				
Nerve, Peripheral				
Ovary	X			
Oviduct				
Pancreas				
Site, Injection		X	X	X
Skin				
Small Intestine, Duodenum				
Small Intestine, Ileum				
Small Intestine, Jejunum				
Spinal Cord				
Spleen	X	X	X	X

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Tissues Collected	Organs Weighed (All Dose Groups)	Tissues Processed for Slide Preparation (X) Dose Group		
		Group 1	Group 2	Group 3
Stomach				
Testis	X			
Thymus	X			
Tongue				
Trachea				
Ureter				
Urinary Bladder				
Uterus				
Vagina				

2.1.3. Organ Weights

Designated organs from animals in Groups 1-3 were weighed at scheduled necropsy. Organ-to-body weight and organ-to-brain weight ratios were calculated.

2.1.4. Tissue Processing

Representative samples of collected tissues were fixed in 10% neutral buffered formalin except for eye with optic nerve attached (Davidson's), and testis and epididymis (modified Davidson's). All tissues processed for slide preparation were stained with hematoxylin and eosin.

2.1.5. Microscopic Examination

For the dosing phase, all tissues (excluding larynx) collected from all dosing phase animals were examined microscopically. For the recovery phase, tissues (bone marrow sternum, joint, liver, draining lymph node, inguinal lymph node, injection site, and spleen) from recovery animals in the control group and test article dose groups were examined microscopically. Microscopic findings were graded on a scale of 1 to 5 as minimal, mild, moderate, marked, or severe; findings not graded were listed as present.

2.1.6. Peer Review

Following completion of the tissue evaluation by the Anatomic Pathologists, a peer review evaluation was performed by another Pfizer Pathologist.

2.2. Statistical Analysis

Statistical analyses of organ weight data were conducted in Pristima with the methods outlined below. All analyses were performed separately for each sex.

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Descriptive statistics were generated for each parameter and group at each scheduled sampling time or each time interval. Statistical tests were conducted at the 5% and 1% significance levels.

Analyses of organ weight parameters were done on measurements collected for each animal at the scheduled sampling times or time intervals. In addition, organ weight to body weight and organ weight to brain weight ratios were analyzed.

A nonparametric (rank-transform) one way analysis of variance (ANOVA) on all groups was conducted, with two-sided pairwise comparisons of Groups 2 and 3 to Group 1 using Dunnett's test. Average ranks were assigned to ties.

3. DATA ACQUISITION

Pristima Preclinical Data Management Suite (Version 7.4.3) was used to record pathology data.

4. DATA MANAGEMENT AND ARCHIVES

Raw data, documentation, protocol and amendments, final report, and any specimens generated at the Test Facility as the result of the study are retained at Pfizer, Groton, CT.

Materials including raw data and documents electronically archived are retained in the Pfizer OpenLab archive system or locked and retained in the source computerized system, as defined per SOP.

Materials are retained in accordance with the Enterprise Records Retention Schedule.

5. RESULTS

5.1. Unscheduled Euthanasia and Deaths

All animals survived until scheduled necropsy.

5.2. Postmortem Observations

5.2.1. Organ Weights

Group mean organ weight data are presented in Table 9. Individual animal organ weight data are included in Appendix 10. Results indicated below are test article group mean values compared with control group mean values.

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Dosing Phase

Test article-related organ weight changes included higher absolute and relative (to body and brain weight) spleen weights in males and females administered BNT162b2 (V9) or BNT162b3c.

Higher group mean absolute and relative spleen weights were noted at 30 µg RNA/dosing day in BNT162b2 (V9) administered males (1.29x – 1.42x) and females (1.55x – 1.62x) and BNT162b3c administered males (1.34x – 1.52x) and females (1.41x – 1.47x) relative to control group means.

Text Table 1. Ratios of Test Article-Related Mean Absolute and Relative (To Body Weight and Brain Weight) Organ Weights Compared with Mean Controls

		Males			Females		
Dose (µg RNA/dosing day)		0	30[d]	30[e]	0	30[d]	30[e]
		Mean	Ratio		Mean	Ratio	
Spleen	Absolute (g)	0.5951	**1.29x**	**1.34x**	0.4382	**1.55x**	**1.41x**
	OW:BW[a]	0.2008	**1.42x**	**1.52x**	0.2202	**1.59x**	**1.47x**
	OW:BN[b]	0.3120	**1.29x**	**1.34x**	0.2353	**1.62x**	**1.43x**
Brain[c]	Absolute (g)	1.9061	1.01x	1.00x	1.8610	0.96x	0.99x
	OW:BW[a]	0.6449	1.10x	1.13x	0.9383	0.98x	1.02x
Terminal BW[c]	Absolute (g)	296.06	0.92x	0.89x	198.73	0.98x	0.97x

BN = Brain weight; BW = Body weight; g = grams OW = Organ weight.
a. Organ weight relative to terminal body weight.
b. Organ weight relative to brain weight.
c. Included for evaluating organ to brain weight and body weight ratios.
d. BNT162b2(V9)
e. BNT162b3c
Bold = test article related.

Recovery Phase

No test article-related organ weight changes were noted for either test article.

The spleen weights (absolute and relative to brain weight) were statistically increased in males administered BNT162b2 (V9). A similar change was not observed in females administered BNT162b2 (V9). A microscopic correlate was not identified in males (ie, no evidence of increased cellularity of hematopoietic cells), although one male had minimally

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increased cellularity of germinal centers in the spleen. A similar increase in spleen weight was not identified in either males or females administered BNT162b3c. Therefore, the higher spleen weights in recovery males administered BNT162b2 (V9) was considered incidental and unrelated to vaccine administration, consistent with full recovery of the higher spleen weights observed at the end of dosing phase.

Other statistically significant or apparent alterations in mean absolute or relative organ weights were not test article-related because they did not occur in a dose-related pattern, were of low magnitude, lacked a macroscopic or microscopic correlate, occurred only in relative data, or occurred only in absolute data, but lost significance when evaluated relative to brain or body weight.

5.2.2. Macroscopic Findings

An incidence summary of macroscopic observations is presented in Table 10. Individual animal macroscopic observations are included in Appendix 11.

Dosing Phase

Test article-related macroscopic findings included large draining lymph nodes (abnormal size, enlarged) and dark/pale and/or firm injection sites (abnormal color, dark/pale and/or abnormal consistency, firm) in animals administered BNT162b2 (V9) or BNT162b3c, and large spleen and inguinal lymph nodes (abnormal size, enlarged) in animals administered BNT162b3c.

The macroscopic observation of large draining lymph nodes was present in BNT162b2 (V9) administered males and females and BNT162b3c administered females; large inguinal lymph nodes were observed in BNT162b3c administered females; pale/dark injection sites were observed in BNT162b2 (V9) administered males and females and BNT162b3c administered males; and firm injection sites were observed in BNT162b2 (V9) or BNT162b3c administered males and females. The macroscopic observation of enlarged spleen was limited to a single BNT162b3c administered female.

Text Table 2. Group Incidences of Test Article-Related Macroscopic Findings

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[b]	30[c]	0	30[b]	30[c]
Number Examined	10	10	10	10	10	10
Lymph Node, Draining						
Abnormal size, enlarged	-	1	-	-	1	4
Lymph Node, Inguinal						

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Text Table 2. Group Incidences of Test Article-Related Macroscopic Findings - Cont'd

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[b]	30[c]	0	30[b]	30[c]
Number Examined	10	10	10	10	10	10
Abnormal size, enlarged	1[a]	-	-	-	-	2
Site, Injection						
Abnormal color, dark/pale	-	2	1	1	3	-
Abnormal consistency, firm	-	2	2	-	4	7
Spleen						
Abnormal size, enlarged	-	-	-	-	-	1

- = No finding present.
a. = No microscopic correlates.
b. BNT162b2(V9).
c. BNT162b3c.

Recovery Phase

Test article-related macroscopic findings observed at the end of recovery phase were limited to large draining lymph nodes (abnormal size, enlarged) in one male administered BNT162b2 (V9) and 1 female administered BNT162b3c and large inguinal lymph nodes (abnormal size, enlarged) in 1 female administered BNT162b3c, indicating a partial recovery of these findings. Pale/dark and/or firm injection sites and enlarged spleen were not observed at the end of recovery phase in BNT162b2 (V9) or BNT162b3c administered males and females, indicating a complete recovery of these findings.

Text Table 3. Group Incidences of Test Article-Related Macroscopic Findings

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[a]	30[b]	0	30[a]	30[b]
Number Examined	5	5	5	5	5	5
Lymph Node, Draining						
Abnormal size, enlarged	-	1	-	-	-	1
Lymph Node, Inguinal						
Abnormal size, enlarged	-	-	-	-	-	1

- = No finding present.
a. BNT162b2(V9).
b. BNT162b3c.

The remaining macroscopic findings were not test article-related effects because they were consistent with spontaneously occurring findings, the findings were distributed randomly

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among groups, or their appearance was similar to findings in controls from this and/or previous studies.

5.2.3. Microscopic Findings

An expanded incidence summary of microscopic observations is presented in Table 11. Individual animal microscopic observations are included in Appendix 11.

Dosing Phase

Organs with test article-related microscopic findings included the injection site (mixed cell inflammation and edema), draining and inguinal lymph nodes (increased cellularity, plasma cells and germinal centers), liver (hepatocellular vacuolation), spleen (increased cellularity, hematopoietic cells and germinal centers), and bone marrow (increased cellularity, hematopoietic cells) in both males and females administered BNT162b2 (V9) or BNT162b3c. Inflammation at the injection site and increased cellularity of germinal centers in the lymph nodes were also observed in control animals but the incidence and/or severity was/were low and within the limits of the expected normal response to intramuscular injection of saline in these animals.

Text Table 4. Group Incidences (with Severities) of Test Article-Related Microscopic Findings

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[b]	30[c]	0	30[b]	30[c]
Site, Injection[a]	10	10	10	10	10	10
Inflammation	4	10	10	5	10	10
Minimal (Grade 1)	4	-	-	5	-	-
Mild (Grade 2)	-	7	5	-	7	9
Moderate (Grade 3)	-	3	5	-	3	1
Edema	-	9	9	-	10	10
Mild (Grade 2)	-	8	8	-	9	9
Moderate (Grade 3)	-	1	1	-	1	1
Lymph Node, Draining[a]	10	9	10	10	10	10
Increased cellularity, Plasma cell	-	7	8	-	9	7
Minimal (Grade 1)	-	1	4	-	1	1
Mild (Grade 2)	-	4	3	-	1	5
Moderate (Grade 3)	-	2	1	-	7	1
Increased cellularity, Germinal center	2	6	8	2	5	6
Minimal (Grade 1)	1	2	2	1	3	4
Mild (Grade 2)	1	4	6	1	2	2
Lymph Node, Inguinal[a]	9	10	10	10	10	10
Increased cellularity, Plasma cell	-	1	1	-	2	4

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Text Table 4. Group Incidences (with Severities) of Test Article-Related Microscopic Findings - Continued

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[b]	30[c]	0	30[b]	30[c]
Minimal (Grade 1)	-	1	1	-	2	4
Increased cellularity, Germinal center	1	5	6	1	6	9
Minimal (Grade 1)	-	1	1	1	3	6
Mild (Grade 2)	1	4	5	-	3	3
Liver[a]	10	10	10	10	10	10
Vacuolation, Hepatocyte; Periportal	-	5	7	-	10	7
Minimal (Grade 1)	-	5	7	-	10	7
Spleen[a]	10	10	10	10	10	10
Increased cellularity, hematopoietic cell	-	10	10	-	9	10
Minimal (Grade 1)	-	10	10	-	9	10
Increased cellularity, Germinal center	-	5	5	-	6	5
Minimal (Grade 1)	-	5	5	-	6	5
Bone marrow, Sternum[a]	10	10	10	10	10	10
Increased cellularity, hematopoietic cell	-	10	10	-	10	10
Minimal (Grade 1)	-	10	10	-	10	10

- = No finding present.
a. Number examined.
b. BNT162b2(V9).
c. BNT162b3c.

Mixed cell inflammation at the injection site was characterized by large numbers of neutrophils with fewer plasma cells, macrophages, and lymphocytes admixed with abundant pale eosinophilic fluid (edema) and small amounts of cellular debris, fibrin, and hemorrhage. Inflammatory cells frequently infiltrated and expanded the epimysium, perimysium, and endomysium and separated and surrounded the myofibers and/or blood vessels in the skeletal muscle. Occasionally, inflammatory cells extended into the subcutaneous tissue/dermis of the overlying skin and into the extra-capsular tissue of the joint.

Increased cellularity in germinal center was observed in the lymph nodes and spleen compared to controls.

Increased cellularity of plasma cells in the lymph nodes was characterized by infiltration of variable numbers of plasma cells in the cortical, medullary, and subcapsular sinuses. Plasma cells were immature in appearance and were interpreted to likely represent plasmablasts.

Increased cellularity of hematopoietic cells in the bone marrow and spleen was characterized by increased hematopoietic precursor cells (primarily myeloid precursors) within the bone marrow or splenic red pulp compared to controls.

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Vacuolation of the periportal hepatocytes in the liver was characterized by small clear round membrane bound structures within cytoplasm of these cells.

Recovery Phase

Test article-related microscopic findings noted at the end of the dosing phase including edema at the injection site, hepatocellular vacuolation in the liver, and increased cellularity of hematopoietic cells in the spleen and bone marrow were not observed at the end of recovery phase in BNT162b2 (V9) or BNT162b3c administered males and females, indicating a complete recovery of these findings. Inflammation at the injection site was characterized by mostly lymphocytes and plasma cells with few neutrophils (indicating partial recovery) and no edema (full recovery). However, increased cellularity of plasma cells and germinal centers in the draining and inguinal lymph nodes, and increased cellularity of the germinal centers in the spleen partially recovered, as the incidence and/or severity of these findings were lower in recovery phase animals as compared to dosing phase animals in both males and females administered BNT162b2 (V9) or BNT162b3c. At the end of recovery phase, mature plasma cells had replaced the plasmablasts identified in the inguinal and draining lymph nodes in the dosing phase animals. In recovery phase animals, infiltration of macrophages was observed in the draining lymph nodes (minimal to mild) in both sexes administered BNT162b2 (V9) or BNT162b3c and in the inguinal lymph nodes (minimal) in both sexes administered BNT162b3c. This finding was considered indicative of a reparative process (consequence of phagocytosis), which can be seen following inflammatory reactions at the injection sites.

Text Table 5. Group Incidences (with Severities) of Test Article-Related Microscopic Findings

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[b]	30[c]	0	30[b]	30[c]
Site, Injection[a]	5	5	5	5	5	5
Inflammation	-	5	5	-	5	5
Minimal (Grade 1)	-	5	5	-	5	5
Lymph Node, Draining[a]	4	5	5	5	5	5
Increased cellularity, Plasma cell	-	4	5	-	4	3
Minimal (Grade 1)	-	4	5	-	4	3
Increased cellularity, Germinal center	-	4	4	1	3	5
Minimal (Grade 1)	-	3	2	1	2	4
Mild (Grade 2)	-	1	2	-	1	1
Infiltration, Macrophage	-	3	4	-	3	4
Minimal (Grade 1)	-	2	2	-	1	1
Mild (Grade 2)	-	1	2	-	2	3

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Text Table 5. Group Incidences (with Severities) of Test Article-Related Microscopic Findings - Continued

Finding	Males Dose (µg RNA/dosing day)			Females Dose (µg RNA/dosing day)		
	0	30[b]	30[c]	0	30[b]	30[c]
Lymph Node, Inguinal[a]	5	5	5	5	5	5
Increased cellularity, Plasma cell	-	-	-	-	-	1
Minimal (Grade 1)	-	-	-	-	-	1
Increased cellularity, Germinal center	2	3	2	2	1	3
Minimal (Grade 1)	2	3	2	2	1	3
Infiltration, Macrophage	-	-	1	-	-	1
Minimal (Grade 1)	-	-	1	-	-	1
Spleen[a]	5	5	5	5	5	5
Increased cellularity, Germinal center	-	1	1	-	2	2
Minimal (Grade 1)	-	1	1	-	2	2

- = No finding present.
a. Number examined.
b. BNT162b2(V9).
c. BNT162b3c.

The remaining microscopic findings were not test article-related effects because they were consistent with spontaneously occurring findings, the findings were distributed randomly among groups, or their appearance was similar to findings in controls from this and/or previous studies.

6. INTEGRATED SUMMARY AND DISCUSSION OF RESULTS

BNT162b2 (Version 9 [V9]) and BNT162b3c, candidate COVID-19 vaccines, were administered by intramuscular (IM) doses once weekly for a total of 3 doses to male and female Wistar Han (Crl:WI[Han]) rats at 30 µg RNA/dosing day followed by a 3-week recovery phase.

All test article-related pathology findings with both vaccine candidates were interpreted as nonadverse, as there was no evidence of systemic toxicity or clinical signs of illness or lameness.

At the end of the dosing phase, test article-related mixed cell inflammation (mild to moderate) and edema (mild to moderate) at the injection site were consistent with those typically associated with the IM administration of lipid nanoparticle (LNP)-encapsulated mRNA vaccines (Hassett et al, 2019). These findings correlated with macroscopic observations of abnormal color (dark/pale) and consistency (firm). At the end of the 3-week recovery phase, full recovery occurred for macroscopic findings of pale/dark and firm

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injection sites and the microscopic finding of edema, whereas partial recovery occurred for inflammation at the injection sites.

At the end of the dosing phase, test article-related findings in the lymph nodes (increased cellularity of plasma cells [minimal to moderate] and germinal centers [minimal to mild]), spleen (increased cellularity of hematopoietic cells [minimal] and germinal centers [minimal]), and the bone marrow (minimal increased cellularity of hematopoietic cells) were secondary to immune activation and/or inflammation at the injection site. The presence of plasma cells (interpreted as plasmablasts) in the draining and inguinal lymph nodes was interpreted to reflect a robust immunological response to the vaccines. These observations correlated with macroscopic observations of abnormal size (enlarged) in the lymph nodes and spleen and increased splenic weights. At the end of the 3-week recovery phase, full recovery occurred for higher spleen weights, macroscopic finding of enlarged spleen, and microscopic findings of increased cellularity of hematopoietic cells in the spleen and bone marrow, whereas partial recovery occurred for macroscopic findings of enlarged draining and inguinal lymph nodes, microscopic findings of increased cellularity of plasma cells and germinal centers in the draining and inguinal lymph nodes, and increased cellularity of the germinal centers in the spleen.

At the end of the dosing phase, test article-related microscopic finding of minimal portal hepatocyte vacuolation was not associated with hepatic tissue damage or liver enzyme alterations. This change might be related to hepatic clearance of the pegylated lipid in the LNP (Ivens et al, 2015). At the end of 3-week recovery phase, this finding was completely recovered.

In conclusion, administration of BNT162b2 (Version 9 [V9]) or BNT162b3c, at 30 µg RNA/dosing day by intramuscular (IM) administration once weekly to Wistar Han rats for 3 weeks did not result in any adverse findings. All test article-related effects were nonadverse, and except for hepatocyte vacuolation, effects were consistent with expected immune responses to vaccines and/or secondary to inflammation. Full or partial recovery occurred in both males and females administered BNT162b2 (V9) or BNT162b3c for all findings by the end of the recovery phase.

7. REFERENCES

Hassett KJ, Benenato KE, Jacquinet E, et al. Optimization of lipid nanoparticles for intramuscular administration of mRNA vaccines. Mol Ther Nucleic Acids 2019;15:1-11.

Ivens IA, Achanzar W, Baumann A, et al. PEGylated biopharmaceuticals: current experience and considerations for nonclinical development. Toxicol Pathol 2015;43(7):959-83.

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Anatomic Pathology Report for Study 20GR142

Medical Quality Assurance

Quality Assurance Statement

Title: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study: 20GR142

In accordance with Pfizer policies and Medical Quality Assurance procedures for Good Laboratory Practice (GLP), the conduct of this portion of this study has been inspected and/or audited as follows.

Phase Inspected	Audit/Inspection Date GMT	Reporting Date GMT
Test Site Protocol Review	24-Jun-2020 to 25-Jun-2020	25-Jun-2020
Protocol Amendment #1	02-Jul-2020 to 02-Jul-2020	02-Jul-2020
Protocol Amendment #4	04-Sep-2020 to 04-Sep-2020	04-Sep-2020
Report: Clinical Pathology	20-Oct-2020 to 30-Oct-2020	03-Nov-2020
Report: Pathology	20-Oct-2020 to 30-Oct-2020	03-Nov-2020

In addition Routine Facility and Process audits are conducted in accordance with MQA SOPs and Site Monitoring Plans.

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Document Approval Record

Document Name:	Anatomic Pathology
Document Title:	20GR142 Anatomic Pathology

Signed By:	Date(GMT)	Signing Capacity
s 22	09-Nov-2020 17:49:26	Quality Assurance Approval
s 22	09-Nov-2020 17:55:46	Scientific Review
s 22	09-Nov-2020 19:54:09	Author Approval

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Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBP020.2LNP
Lot: CoVVAC/270320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 09.04.20 s 22

Date: 09.04.20

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Non-GMP CoA

Material not for human use
Version 2

Product: **CorVac BNT162b3c**
Batch: RBP020.8 LNP
Lot: BCV/040620

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	s 47
RNA identity	CE (223/SOP/015)	
RNA integrity	CE (223/SOP/015)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 identification and content	HPLC-CAD (222/SOP/044)	
ALC-0159 identification and content	HPLC-CAD (222/SOP/044)	
DSPC identification and content	HPLC-CAD (222/SOP/044)	
Cholesterol identification and content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 03.07.2020

Date: 03.07.2020

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Medical Quality Assurance

Quality Assurance Statement

Title: 17-DAY INTRAMUSCULAR TOXICITY STUDY OF BNT162B2 (V9) AND BNT162B3C IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY

Study: 20GR142

In accordance with Pfizer policies and Medical Research Quality Assurance procedures for Good Laboratory Practice (GLP), the conduct of this study has been inspected and/or audited as follows. The Individual Quality Assurance Statement for study phase(s) conducted at other site(s) are contained within this report.

Phase Inspected	Audit/Inspection Date GMT	Reporting Date GMT
Protocol Review	29-Jun-2020 to 29-Jun-2020	30-Jun-2020
Protocol Amendment #1	07-Jul-2020 to 07-Jul-2020	07-Jul-2020
In-life: Dosing	13-Jul-2020 to 14-Jul-2020	16-Jul-2020
In-life: Dosing	13-Jul-2020 to 14-Jul-2020	16-Jul-2020
Protocol Amendment #2	16-Jul-2020 to 16-Jul-2020	16-Jul-2020
In-life: Clin Path Blood Collection	22-Jul-2020 to 23-Jul-2020	24-Jul-2020
In-life: Necropsy	22-Jul-2020 to 22-Jul-2020	24-Jul-2020
Protocol Amendment #3	28-Jul-2020 to 28-Jul-2020	03-Aug-2020
Protocol Amendment #4	08-Sep-2020 to 08-Sep-2020	08-Sep-2020
Report: Nonclinical Study	14-Oct-2020 to 03-Nov-2020	03-Nov-2020

In addition Routine Facility and Process audits are conducted in accordance with MQA SOPs and Site Monitoring Plans.

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Document Approval Record

Document Name:	Study 20GR142 - 17-Day Intramuscular Toxicity Study of BNT162B2 (V9) and BNT162B3C in Wistar Han Rats with a 3-Week Recovery
Document Title:	Final Report - 17-Day Intramuscular Toxicity Study of BNT162B2 (V9) and BNT162B3C in Wistar Han Rats with a 3-Week Recovery

Signed By:	Date(GMT)	Signing Capacity
s 22	13-Nov-2020 15:16:04	Quality Assurance Approval
s 22	13-Nov-2020 15:24:46	Author Approval

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charles river

FINAL REPORT

Testing Facility Study No. 513351

Sponsor Reference No. 1156PM

AstraZeneca Project Name: AZD1222

AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

SPONSOR:
AstraZeneca R&D Cambridge
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Cambridge Road, Melbourn
Hertfordshire SG8 6HB, UK

TESTING FACILITY:
Charles River Laboratories Edinburgh Ltd
Elphinstone Research Centre
Tranent, East Lothian
EH33 2NE, UK

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QUALITY ASSURANCE STATEMENT

Study Number: 513351

Study Title: AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

The Charles River Quality Assurance Unit conducted a protocol review, protocol amendment reviews, study-based inspections and report audits on this study, as detailed below.

QA INSPECTION DATES

		Dates Findings Submitted to:	
Date(s) of Audit	Phase(s) Audited	Study Director	Study Director Management
31-Aug-2020	Final Protocol	31-Aug-2020	31-Aug-2020
04-Sep-2020	Protocol Amendment 01	07-Sep-2020	07-Sep-2020
08-Sep-2020	Dose Administration	08-Sep-2020	08-Sep-2020
08-Sep-2020	Protocol Amendment 02	08-Sep-2020	08-Sep-2020
08-Sep-2020	Dose Preparation	17-Sep-2020	17-Sep-2020
09-Sep-2020	Protocol Amendment 03	09-Sep-2020	09-Sep-2020
02-Oct-2020	Protocol Amendment 04	02-Oct-2020	02-Oct-2020
16-Oct-2020	Protocol Amendment 05	16-Oct-2020	16-Oct-2020
26-Oct-2020	Protocol Amendment 06	28-Oct-2020	28-Oct-2020
15-Nov-2020	Protocol Amendment 07	15-Nov-2020	15-Nov-2020
15-Nov-2020	Protocol Amendment 08	15-Nov-2020	15-Nov-2020
24-Nov-2020	Protocol Amendment 09	26-Nov-2020	26-Nov-2020
24-Nov-2020	Protocol Amendment 10	04-Dec-2020	04-Dec-2020
02-Dec-2020 - 04-Dec-2020 07-Dec-2020 - 08-Dec-2020	Report	08-Dec-2020	08-Dec-2020
02-Dec-2020 - 04-Dec-2020 07-Dec-2020 - 08-Dec-2020	Data Review - Animal Care	08-Dec-2020	08-Dec-2020
03-Dec-2020	Data Review - Necropsy	08-Dec-2020	08-Dec-2020
07-Dec-2020	Data Review - Formulations	07-Dec-2020	07-Dec-2020
07-Dec-2020 - 08-Dec-2020	Necropsy	08-Dec-2020	08-Dec-2020
07-Dec-2020	Protocol Amendment 11	07-Dec-2020	07-Dec-2020
11-Dec-2020	Protocol Amendment 12	11-Dec-2020	11-Dec-2020
11-Dec-2020	Protocol Amendment 13	11-Dec-2020	11-Dec-2020
30-Dec-2020	Final Report	30-Dec-2020	30-Dec-2020

Process-based inspections relevant to this study are scheduled once every quarter. The outcome of each inspection is reported to Management and, where relevant, the Study Director.

Facilities relevant to this study are included in Charles River's annual facility inspection programme. The outcome of each inspection is reported to Management.

QUALITY ASSURANCE STATEMENT (CONTINUED)

Study Number: 513351

Study Title: AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

This report is considered to describe accurately and completely the procedures used in the study and the results obtained.

The Quality Assurance statement for the work conducted at AstraZeneca, Aaron Klug Building, Granta Park, Cambridge, CB21 6GH, UK (immunogenicity) is included in the Principal Investigator's phase report presented in Appendix 13.

Quality Assurance Auditor

COMPLIANCE STATEMENT AND REPORT APPROVAL

Study Number: 513351

Study Title: AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

The study, with the exception of the stability of the test item and pathology peer review, was performed in accordance with the OECD Principles of Good Laboratory Practice as incorporated into the United Kingdom Statutory Instrument for GLP and as accepted by Regulatory Authorities throughout the European Union, United States of America (FDA and EPA) and Japan (MHLW, MAFF and METI) and other countries that are signatories to the OECD Mutual Acceptance of Data Agreement.

A Compliance Statement from the Principal Investigator for the immunogenicity work conducted at AstraZeneca, Aaron Klug Building, Granta Park, Cambridge, CB21 6GH, UK is presented in Appendix 13.

SEND datasets were not subject to QA Audit nor used as the basis for the Study Director interpretation of the final study results.

Exceptions from the above regulations are listed below.

- Pathology Peer Review
- Stability Assessment of the Test Item

This study was conducted in accordance with the procedures described herein. All deviations authorised/acknowledged by the Study Director are documented in the study records and have no impact on the outcome or integrity of the study. The report represents an accurate and complete record of the results obtained.

Study Director

1. RESPONSIBLE PERSONNEL

Role/Phase	Name	Location
Study Director	s 22	Address as cited for Test Facility
Test Facility Management		Address as cited for Test Facility
Sponsor Representative (Study Monitor)		AstraZeneca R&D Cambridge da Vinci Building Melbourn Science Park Cambridge Road, Melbourn Hertfordshire, SG8 6HB, UK
Individual Scientist (IS) - Irwin Measurements		Address as cited for Test Facility
Individual Scientist (IS) - Pathology		Address as cited for Test Facility
Contributing Scientist (CS) – Immunogenicity Interpretation		Address as cited for Test Facility
Principal Investigator (PI) - Immunogenicity		AstraZeneca Aaron Klug Building Granta Park, Cambridge CB21 6GH, UK
Clinical Pathology Review		Charles River Laboratories Preclinical Services, Nevada 6995 Longley Lane Reno, NV 89511, USA

2. SUMMARY

AZD1222 is a recombinant, replicant defective adenovirus (ChAdOx1-nCovd-19) expressing the SARS-CoV-2 spike (S) surface glycoprotein which is under development by AstraZeneca as a potential COVID-19 disease prevention vaccine. The objective of this study was to determine the potential toxicity of AZD1222 when given by intramuscular injection intermittently (on Days 1, 22 and 43) to mice, with a 28 day recovery period to evaluate the potential reversibility of any findings. In addition, the immunogenicity was evaluated. Scheduled necropsies were conducted either at the end of the 6 week treatment period (Day 45) or at the end of the 28 day recovery period.

The study design was as follows:

Text Table 1
Experimental Design

Group No.	Treatment	Dose Volume[a] (µL)	Total Viral Particle (VP)/dose
1	Control	70	0
2	AZD1222	70	3.7×10^{10}

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 70 µL [0.07 mL])
Control item = AZD1222 Vehicle (10 mM histidine, 7.5% [v/w] sucrose, 35 mM sodium chloride, 1 mM magnesium chloride, 0.1% [v/w] Polysorbate-80, 0.1 mM EDTA and 0.5% [v/w] ethanol, pH 6.6)

Text Table 2
Number of Animals

Group No.	Main Study		Recovery		Immunogenicity	
	M	F	M	F	M	F
1	20	20	20	20	-	-
2	20	20	20	20	5	5

- = Not applicable, M = Males, F = Females

The following parameters and end points were evaluated in this study: clinical signs, body temperature, body weights, body weight gains, food consumption, dermal scoring, Irwin screen observations, clinical pathology parameters (hematology and plasma chemistry), immunogenicity, gross necropsy findings, organ weights, and histopathological examinations.

In comparison to controls and pre-study data, a slightly higher body temperature was observed in AZD1222 treated males, notably on Days 22, 4 hours post dose (range 36.2-39.5ºC compared to 36.2-38.7ºC in controls) but was comparable to controls by 24 hours post-dose. There was no AZD1222-related change in body temperature recorded in males, as part of the Irwin observations.

In animals administered AZD1222, there was a mild decrease in monocytes on Day 45, which was consistent with expected pharmacology following immunisation. Additionally, globulin was mildly higher, and albumin and albumin/globulin ratio were minimally to mildly lower, which was consistent with an acute phase response. Following the recovery period, globulin remained mildly higher and albumin/globulin ratio remained mildly lower in AZD1222-treated females, the other changes had reversed.

All samples collected from animals during the pretreatment phase prior to immunisation were below the limit of quantification (BLQ) for the assay (BLQ; 0.250 AU/mL) and considered

seronegative. Samples collected indicate that all animals mounted an antibody response to S-glycoprotein following a single administration of AZD1222 on Day 1 with most animals showing a marked increase in the level of antibody response following a second administration of AZD1222 on Day 22. On Day 74, a further increase in antibody response or maintenance of response was observed in all animals following a third administration of AZD1222.

At histopathological examination of the main study animals, mononuclear and/or mixed cell inflammation was observed in the subcutaneous tissue and underlying skeletal muscle at the control and AZD1222 administration sites. This finding was of a higher incidence in animals dosed with AZD1222. In some animals there was an extension of the inflammatory cells into the fascia and connective tissue below the skeletal muscle at the administration sites, that extended to surround the sciatic nerve. The inflammatory cells did not extend into the endoneurium of the sciatic nerve and no findings were present in the underlying axons, which appeared histologically normal. Inflammatory cells were not observed in the nerve roots contained within the lumbar spinal cord sections, confirming that the epineurial/perineurial inflammatory cells noted in the sciatic nerve samples resulted from an extension of the inflammation from the adjacent injection site. There were no findings in the administration sites or sciatic nerves at the end of the recovery period, indicating complete recovery of the AZD1222 related inflammation.

In conclusion, administration of AZD1222 to CD-1 mice (total viral particle dose of $3.7x10^{10}$) by intramuscular injection on 3 occasions (once every 3 weeks) over a 43 day period was well tolerated, with a transiently higher body temperature in males, decreases in monocytes in males and females (consistent with the expected pharmacology of AZD1222) and increase in globulin and decrease in albumin and albumin/globulin ratio, consistent with an acute phase response, observed.

In all animals dosed with AZD1222, antibodies against the S-glycoprotein were raised and maintained throughout the dosing and recovery periods in all animals.

In AZD1222 animals, higher spleen weights were observed but with no correlating macroscopic or microscopic changes. Non adverse, fully reversible, mixed and/or mononuclear cell inflammation was observed in the subcutaneous tissues and skeletal muscle of the administration sites and adjacent sciatic nerve of animals dosed with AZD1222 which were consistent with the anticipated findings after intra-muscular injection of vaccines.

3. INTRODUCTION

AZD1222 is a recombinant, replicant defective adenovirus (ChAdOx1-nCovd-19) expressing the SARS-CoV-2 spike (S) surface glycoprotein which is under development by AstraZeneca as a potential COVID-19 disease prevention vaccine. The objective of this study was to determine the potential toxicity of AZD1222 when given by intramuscular injection intermittently (on Days 1, 22 and 43) to mice with a minimum 28 day recovery period to evaluate the potential reversibility of any findings. In addition, the immunogenicity was evaluated.

The design of this study was based on the study objectives, the overall product development strategy for the test item, and the following study design guidelines:

- ICH Harmonised Tripartite Guideline S7A. *Guideline on Safety Pharmacology Studies for Human Pharmaceuticals*.
- Committee for Medicinal Products for Human Use (CHMP). *Note for Guidance on Repeated Dose Toxicity*. CPMP/SWP/1042/99rev1.
- ICH Harmonised Tripartite Guideline M3 (R2). *Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals.*
- WHO Guideline on Nonclinical Evaluation of Vaccines, Nov 2005, and WHO Guideline on the Nonclinical Evaluation of Vaccine Adjuvants and Adjuvanted vaccines Oct 2013.
- FDA: Guideline for Industry: Considerations for Development Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications 2006, and Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry; Center for Biologics Evaluation and Research; June 2020.
- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Number 13. *Consensus Document of the Working Group on Good Laboratory Practice. The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies*.

Study Initiation Date:	25 August 2020
Initiation of Dosing:	08 September 2020
Completion of In-life:	20 November 2020 (last date of necropsy)
Experimental Starting Date:	01 September 2020
Experimental Completion Date:	30 December 2020

4. MATERIALS AND METHODS

4.1. Study design

Text Table 3
Experimental Design

Group No.	Treatment	Dose Volume[a] (µL)	Total Viral Particle (VP)/dose
1	Control	70	0
2	AZD1222	70	3.7×10^{10}

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 70 µL [0.07 mL])

Text Table 4
Animal Numbers

Group No.	Animal Numbers					
	Main Study		Recovery		Immunogenicity	
	M	F	M	F	M	F
1	1001-1020	1501-1520	1101-1120	1601-1620	-	-
2	2001-2020	2501-2520	2101-2120	2601-2620	2201-2205	2701-2705

- = Not applicable; M = Male, F = Female

The study was conducted in accordance with the Study Protocol presented in Appendix 1. Deviations to the Study Protocol are presented in Section 4.3.

Text Table 5
Protocol Specifications

Age at Initiation of Dosing	7-8 weeks old
Body Weight Range at Initiation of Dosing	31.0 – 40.4 g males 21.2 – 30.6 g females
Environmental Conditions	Temperature – Target 19-23°C; Actual 19-23°C Humidity – Target 40-70%; Actual 31-67%
Number of Acclimation Days	14 days
Animal Enrichment	In addition to the enrichment items stated in the protocol, nestlets were also provided to the cages.

Text Table 6
Study Events

Event	Impact
Animal F1618 was found dead on Day 39.	As this was a control animal, there were still sufficient data within the group to allow a meaningful toxicological evaluation of AZD1222 and therefore, this was considered to have had no impact on the outcome or integrity of the study.
At dosing on Day 22, part of the dose for Animal M1105 was administered subcutaneously instead of the intramuscular (I/M) route.	As this was a control animal, there was still sufficient data within the group to allow a meaningful toxicological evaluation of AZD1222 and therefore, this was considered to have had no impact on the outcome or integrity of the study.

Event	Impact
The target range for humidity was 40 to 70%, however, the actual range was 31 to 67%.	There were occasions where the target environmental conditions for humidity were not maintained. These occasions were transient, and the health of the animals was unaffected on any occasion, therefore, these excursions were considered not to impact the outcome or integrity of the study.

4.2. Test material identification

Text Table 7
Test Item Identification

	Test Item	Control Item
Identification	AZD1222	AZD1222 Vehicle Buffer
Alternate Identification	ChAdOx-nCovd-19	-
Batch/Lot No.	MS00684-92	BN20-1689
Expiration/Retest Date	07 Aug 2021	24 Feb 2021
Viral Particle Concentration	5.3 x10^{11}/mL	-
Density	1.025 g/cm^3	1.029 g/cm^3
Storage Conditions	Set to maintain -80°C	Set to maintain 4°C
Provided by	Sponsor	Sponsor

- = Not applicable
Control Item; AZD1222 vehicle = 10 mM histidine, 7.5% [v/w] sucrose, 35 mM sodium chloride, 1 mM magnesium chloride, 0.1% [v/w] Polysorbate-80, 0.1 mM EDTA and 0.5% [v/w] ethanol, pH 6.6)

4.3. Protocol deviations

All deviations that occurred during the study have been authorised/acknowledged by the Study Director, assessed for impact, and documented in the study records. All protocol deviations and those SOP deviations that could have impacted the quality or integrity of the study are listed below. Minor SOP deviations that did not impact the quality or integrity of the study have been included at the discretion of the Study Director.

None of the deviations were considered to have impacted the overall integrity of the study or the interpretation of the study results and conclusions.

Exception to GLP

- As detailed in the protocol, the peer review of the pathology data was not conducted in accordance with the principles of GLP. As the pathology evaluation was conducted and peer reviewed by board certified pathologists with significant experience in this field, this was considered to have had no impact on the outcome or integrity of the pathology evaluation or the overall study conclusions.
- As detailed in the protocol, the stability of the test item was not conducted in accordance with the principles of GLP but was conducted according to GMP. The test item formulations were used as supplied from the Sponsor. Prior to dosing, the data supplied was reviewed by the Study Director and considered suitable for use on this study. As the stability of the

formulation was conducted in accordance with GMP, it was considered to have had no impact on the outcome or integrity of the study.

Formulations and Dosing

- The protocol stated that the pre-supplied control item would be removed from the freezer on the morning of dosing, however, on the first two dosing occasions, the control item was instead removed from the refrigerator. As the control item was stored in the refrigerator, the protocol should have stated that it would be removed from the refrigerator, not the freezer. Therefore, this was considered to have no impact on the outcome or integrity of the study as the control item was handled as intended.
- The protocol stated that a reserve sample of the test item would not be retained at the Test Facility, however, a reserve sample of the test item was retained at the Test Facility under a different study that used the same test item. This did not prevent the study objectives from being met and as the sample was not retained under this study, this was considered to have had no impact on the outcome or integrity of the study.

In-life Observations, Measurements, and Evaluations

- On Day 1, the 3 to 4 hours post administration observations for Group 2 animals were recorded up to 7 minutes late. This was considered to be a minimal time deviation and therefore, this was considered to have had no impact on the outcome or integrity of the study.
- On Day 1, the 3 to 4 hours post administration observations for Group 1 animals were not recorded. The animals were free from clinical observations at the previous and subsequent time points. Additionally, the animals had body temperatures and dermal scoring recorded at 4 hours post-dose and so the Study Director was confident that the animals were observed and were free from clinical observations.
- On Day 1, the pre-administration dermal scoring for Site 1 for Animal M2004 was incorrectly recorded as the right leg for erythema, however this should have been recorded as the left leg. This was considered to be a data recording error and the Study Director was confident that the left hindlimb was also assessed and free from erythema and oedema. Therefore, this was considered to have no impact on the outcome or integrity of the study.
- Dermal scoring was recorded for all animals on Day 23 despite this not being required by the protocol. The observation of animals at an additional time point did not prevent the study objectives from being met and therefore, this was considered to have no impact on the outcome or integrity of the study.
- The protocol stated that the dermal scoring procedure would be conducted at 4 hours post each dosing occasion, however, on several occasions throughout the study, this was recorded up to 32 minutes early and/or up to 9 minutes late. These were generally considered to be minimal time deviations and did not prevent a meaningful evaluation of this data set and therefore, this was considered to have had no impact on the outcome or integrity of the study.
- The recovery and immunogenicity animals had an additional body weight collected on Day 46, in error. This additional data did not prevent the study objectives from being met and therefore, this was considered to have had no impact on the outcome or integrity of the study.

- The immunogenicity animals did not have food consumption recorded throughout the recovery period in error. As food consumption was measured in recovery animals throughout this period, there was sufficient data to allow a meaningful evaluation of this data set and therefore, this was considered to have had no impact on the outcome or integrity of the study.
- On Day 22 for one control male, food consumption was not calculable due to a food recording error. As there was sufficient data within the group to allow a meaningful analysis of the data, this was considered to have had no impact on the outcome or integrity of the study.
- The Day 1, 24 hour (±1 hour) body temperature for AZD1222-treated males were recorded up to 1 hour and 15 minutes outside the protocolled allowance. This did not prevent a meaningful evaluation of this data set and therefore, this was considered to have had no impact on the outcome or integrity of the study.

Postmortem and Pathology

- The Study Director issued a signed instruction that detailed the order in which the animals should be euthanised, however, at the main study necropsy, one animal was killed out of the specified order and at the recovery necropsy, 5 animals were killed out of the specified order. Animals were rotated across the groups and sexes throughout the day and this did not prevent the study objectives from being met, therefore this was considered to have no impact on the outcome or integrity of the study.
- On Day 74, both ovaries for Animal F1601 were lost at necropsy prior to a weight being collected and they were therefore not available for histopathological evaluation. There was still sufficient data within the group to allow a meaningful analysis of the data set and therefore, this was considered to have had no impact on the outcome or integrity of the study.
- The protocol stated that the immunogenicity animals would be euthanised by an approved method, however, there is no positive confirmation of the method of euthanasia within the study data. At the Test Facility, the only methods of euthanasia are approved methods and so the Study Director is confident an approved method was used despite the lack of positive confirmation of this. There were no terminal procedures on these animals and therefore, this was considered to have had no impact on the outcome or integrity of the study.

Statistical Analysis

- Body temperature was incorrectly omitted from the statistical analysis section of the protocol; however, these analyses were performed. Data were scheduled to be collected, with the intention to analyse the data as is standard on this data type. As the intention of the study was carried out as planned, this deviation is deemed to have had no impact on the integrity or outcome of the study.

5. COMPUTERISED SYSTEMS

Critical computerised systems used in the study are listed below or presented in the appropriate Phase Report. All computerised systems used in the conduct of this study have been validated.

Text Table 8
Critical Computerised Systems

System Name	Version No.	Description of Data Collected and/or Analysed
Provantis®	10	Applicable in-life, clinical pathology and postmortem
Dispense	10	Test item receipt, accountability and formulation activities.
MSD SECTOR S 600	Asset number 200034966	Immunogenicity
MSD Analysis Software	4.0.12	Immunogenicity
Devil Information Library	2.1	Study deviations
Share Document Management System (SDMS)	1.0	Reporting
DocuSign™	19	Collection of 21 CFR Part 11 Compliant signatures
Vaisala/Trend 963 Secure	1.22	Continuous temperature and humidity recording. Alarms for animal rooms, refrigerators, freezers and incubators.
eSlide manager	12.4.3.7006	Histopathology peer review

6. RETENTION OF RECORDS, SAMPLES, AND SPECIMENS

All study-specific raw data, documentation, protocol, protocol amendments, samples, specimens, and Final Reports from this study were archived at the Test Facility, unless otherwise stated below. Three years after issue of the Final Report, the Sponsor will be contacted.

On completion of the immunogenicity phase, all raw data and study related documents generated during this phase of this study, including a copy of the Phase Plan (and all associated amendments), and Final Phase Report, will be stored initially in the archives at AstraZeneca, Cambridge, UK. Periodically records will be transferred to an off-site contract archive facility, Qualogy (UK) as per the Global Retention and Destruction (GRAD) schedule.

Study samples are stored initially in Integrated Bioanalysis laboratory at AstraZeneca, Cambridge, UK. Periodically material may be transferred to an off-site contract archive facility, Cryostore, UK for a period of at least 2 years or as stated in the Study Protocol. Electronic data generated by the Test Facility were archived as noted above, except that the data collected using Provantis and Dispense, reporting files stored on SDMS, and study deviations recording on Devil Information Library were archived at the Charles River Laboratories facility location in Wilmington, MA, USA.

7. RESULTS AND DISCUSSION

7.1. Mortality

(Appendix 2)

Control animal F1618 was found dead on Day 39. There were no clinical observations or erythema/oedema noted at the injection sites in this animal throughout the study and there were no changes in body weight. As this is a control animal, this was considered to be unrelated to administration AZD1222. Many tissues showed post-mortem changes but there were no microscopic findings that would account for the death of this animal.

7.2. Clinical observations

(Table 1 and Appendix 3)

There were no clinical observations that were considered to be related to administration of AZD1222.

Erect fur was observed in all male animals, including controls and in the majority of AZD1222 females throughout the dosing period. In females, this had recovered by Day 25, however, was observed throughout the duration of the dosing period in males. As this was also observed in control animals, it was considered unrelated to administration of AZD1222. Additionally, there were isolated instances of increased activity, eyeball opacity, protruding eyeballs, pale pinnae, hunched posture and repetitive behaviour throughout the study, however, these were either observed at a similar incidence in control and AZD1222 treated animals, a higher incidence in control animals or observed in control animals only and therefore were considered unrelated to administration of AZD1222.

7.3. Body temperatures

(Table 2 and Appendix 4)

Following administration of AZD1222, in comparison to control and pre-study data, a slightly higher body temperature was observed in males on Day 1 and also Day 22, 4 hours post dose. This increase was statistically significant on Day 22 (at 4 hours post dose), with AZD1222 group mean body temperatures of 38.25°C (36.2-39.5°C) compared to 36.98°C (36.2-38.7°C) in the control group. Body temperature was comparable to controls by 24 hours post each dosing occasion. It should be noted that there was individual variability in the body temperature with various individual animals, including controls, showing an increase/decrease in temperature values at the measured intervals. There was no AZD1222-related change in body temperature recorded in males, as part of the Irwin observations (see Section 7.7 and Appendix 10).

In females, there were no changes in body temperature that were considered to be related to administration of AZD1222.

7.4. Body weights and body weight gains

(Figure 1, Table 3, Table 4, Appendix 5, Appendix 6 and Appendix 7)

There were no changes in body weight that were considered to be related to administration of AZD1222. Any changes observed were considered to be due to natural variation and/or were observed during pretreatment and/or in control animals.

7.5. Food consumption

(Table 5 and Appendix 8)

There were no changes in food consumption that were considered to be related to the administration of AZD1222.

7.6. Dermal scoring

(Appendix 9)

There was no erythema or oedema at the injection sites after administration of AZD1222 on any dosing occasion.

7.7. Irwin observations

(Appendix 10)

Following intramuscular administration of AZD1222 at a viral particle dose of 3.7 $x10^{10}$, there were no effects on body temperature, pupil size or Irwin observations, when assessed in males on Day 8 and 29 of the study.

7.8. Haematology

(Table 6 and Appendix 11)

AZD1222-related changes in haematology parameters were limited to a mild decrease in monocytes for males (0.43x) and females (0.39x; statistically significant) on Day 45 that was consistent with expected pharmacology following immunisation. Following a 4-week recovery period, there were no AZD1222-related changes in haematology parameters indicating reversibility of findings noted in the main study animals.

Remaining differences in haematology parameters, none of which attained statistical significance, were considered not AZD1222 related and were attributed to biological variation as similar variations were seen in control values, and/or were of a magnitude of change commonly observed in mice under similar study conditions.

7.9. Plasma chemistry

(Table 7 and Appendix 12)

In comparison with controls, globulin was mildly higher, and albumin and albumin/globulin ratio were minimally to mildly lower in AZD1222-treated males and females on Day 45 that may suggest an acute phase response. Following a 4-week recovery period, globulin remained mildly higher and albumin/globulin ratio remained mildly lower in AZD1222-treated females.

In AZD1222-treated females, creatinine was higher for F2512 and F2513, and F2518. These changes were considered not AZD1222-related due to the low incidence and lack of similar changes in males, and lack of changes in other plasma chemistry parameters.

Text Table 9
AZD1222-related Plasma Chemistry Changes

AZD1222	0		$3.7x10^{10}$	
Sex	**M**	**F**	**M**	**F**
Day 45				
Globulin (g/L)	17.90	15.26	1.19***	1.22**
Albumin (g/L)	31.29	34.85	0.94*	0.90**
Day 74 (recovery period)				
Globulin (g/L)	-	12.95	-	1.19*

Numerical values indicate fold changes of treated group mean value relative to the respective control group mean value.
*Indicates statistical significance $p < 0.05$; ** indicates statistical significance $p < 0.01$; *** indicates statistical significance $p < 0.001$.
- Not applicable

Remaining differences in plasma chemistry parameters, some of which attained statistical significance, were considered not AZD1222 related and were attributed to biological variation as similar variations were seen in control values, and/or were of a magnitude of change commonly observed in mice under similar study conditions.

7.10. Immunogenicity

(Figure 2, Figure 3, Figure 4, Table 8 and Appendix 13)

Mouse serum samples were analysed for the determination of antibodies against the S-glycoprotein raised in response to immunisation with AZD1222.

All samples collected from animals during the pretreatment phase prior to immunisation were below the limit of quantification (BLQ) for the assay (BLQ; 0.250 AU/mL) and considered seronegative.

Antibody response is summarised in Text Table 10.

Text Table 10
Immunogenicity Response: Antibody Concentration (AU/mL)

Day	Males	Females	Males and Females Combined
Day 22			
Mean	372.405	816.330	594.367
SD	305.966	567.711	489.480
Day 43			
Mean	993.835	1636.206	1315.020
SD	812.896	1178.415	1012.667
Day 74 (recovery period)			
Mean	1240.280	2477.321	1858.800
SD	827.750	2089.539	1634.049

Samples collected on Day 22 indicate that all animals mounted an antibody response to S-glycoprotein following a single administration of AZD1222 on Day 1. Day 43 samples indicated a marked increase in the level of antibody response for most animals following a second administration of AZD1222 on Day 22.

On Day 74, a further increase in antibody response or maintenance of response was observed in all animals following a third administration of AZD1222.

7.11. Gross pathology

(Table 11 and Appendix 17)

Main Study Animals

No AZD1222-related gross findings were noted.

Gross findings (dark discoloration) seen at administration site 2 were considered incidental to the injection procedure and/or were of similar incidence in control and animals administered AZD1222 and, therefore, were considered to be procedural and unrelated to administration of AZD1222.

The gross finding observed in the liver of one female administered AZD1222 was of the nature commonly observed in this strain and age of mouse and, therefore, was considered unrelated to administration of AZD1222.

Gross findings are summarised in Text Table 11.

Text Table 11
Salient Gross Findings Main Study

Study Phase	**Main**			
Viral Particle (VP)/dose	**0**	**3.7 x 10^{10}**	**0**	**3.7 x 10^{10}**
Sex	**Males**		**Females**	
Number of animals	**20**	**20**	**20**	**20**
Liver (No. examined)	(20)	(20)	(20)	(20)
Prominent lobular architecture	0	0	0	1
Site Admin, 2 (No. examined)	20	20	20	20
Discoloration, dark	1	2	0	1

Recovery Animals

No AZD1222-related gross findings were noted.

All gross findings observed were of the nature commonly observed in this strain and age of mouse and, therefore, were considered unrelated to administration of AZD1222.

7.12. Organ weights

(Table 9, Table 10, Appendix 14, Appendix 15 and Appendix 16)

Main Study Animals

There was a test item-related higher spleen weight in both sexes, but with no correlating macroscopic or microscopic findings. Organ weight changes are summarised in Text Table 12.

Text Table 12
Salient Organ Weight Data

Study Phase	**Main**			
Sex	**Males**		**Females**	
Viral Particle (VP)/dose	**0**	**3.7 x 10^{10}**	**0**	**3.7 x 10^{10}**
Number of animals	**20**	**20**	**20**	**20**
Mean Terminal Body Weight (No. weighed)	20	20	20	20
Group mean value (g)	37.40	39.01*	29.70	30.44
Spleen (No. weighed)	(20)	(20)	(20)	(20)
Absolute value (g)	0.0910	0.1215***	0.1227	0.1738***
Relative to body weight (%)	0.24370	0.31106***	0.41039	0.56592***

Significantly different from control group 1 value Anova & Dunnett: * = $p \leq 0.05$, *** = $p \leq 0.001$.

Other differences in organs weights were considered unrelated to administration of AZD1222.

Recovery Animals

The test item related higher weight seen in the spleens of main study animals was not present in recovery animals.

Other differences in organs weights were considered unrelated to administration of AZD1222.

7.13. Histopathology

(Table 12, Appendix 17, Appendix 18 and Appendix 19)

Main Study Animals

Minimal subcutaneous oedema was observed in the administration sites in male and female animals from both the control group and those administered AZD1222 and was considered to be related to the route of administration.

Minimal mononuclear or mixed cell inflammation was observed in the subcutaneous tissue and underlying skeletal muscle at the administration sites in both male and female animals. This finding was of a higher incidence in animals administered with AZD1222.

In some animals there was an extension of the inflammatory cells into the fascia and connective tissue below the skeletal muscle at the administration sites. This resulted in inflammatory cells being noted surrounding the epineurium/perineurium of the sciatic nerve samples. This finding was recorded as ‘Inflammation perineurium’ in the histopathology data. While sciatic epineurial/perineurial inflammatory cells were present in a small number of controls, the incidence was higher in animals administered AZD1222, and reflected the higher incidence of inflammatory cells noted at the injection sites of animals administered AZD1222. The epineurial/perineurial inflammatory cells did not extend into the endoneurium, and no findings were present in the underlying axons, which appeared histologically normal. Inflammatory cells were not observed in the nerve roots contained within the lumbar spinal cord sections, confirming that the epineurial/perineurial inflammatory cells noted in the sciatic nerve samples resulted from an extension of the inflammation from the adjacent injection site. In the hind limb,

inflammation around the sciatic nerve due to local extension from the administration site is a well-recognized effect (Sellers, 2019).

Histopathology findings are summarised in Text Table 13.

Text Table 13
Salient Microscopic Findings in the Administration Sites of Main Study Animals

Study phase	**Main**			
Viral Particle (VP)/dose	**0**	**3.7 x 10^{10}**	**0**	**3.7 x 10^{10}**
Number of animals	**10**	**10**	**10**	**10**
Sex	**Males**		**Females**	
Administration site 1 (No. examined)	(10)	(10)	(10)	(10)
Inflammation, subcutaneous tissue; myofiber, minimal	2	10	1	10
Mononuclear cell	2	6	0	3
Mixed cell	0	4	1	7
Oedema, subcutaneous, minimal	8	9	7	5
Haemorrhage, subcutaneous, minimal	0	0	0	1
Administration site 2 (No. examined)	(10)	(10)	(10)	(10)
Inflammation, subcutaneous tissue; myofiber, minimal	4	10	1	9
Mononuclear cell	4	6	0	1
Mixed cell	0	4	1	8
Oedema, subcutaneous, minimal	9	9	10	4
Haemorrhage, subcutaneous, minimal	2	2	0	2
Congestion, subcutaneous, minimal	1	0	0	0
Sciatic Nerve (No. examined)	(10)	(10)	(10)	(10)
Inflammation, perineurial, minimal	0	9	2	9
Mononuclear cell	0	5	0	1
Mixed cell	0	4	2	8

The inflammation observed at the administration sites was of the nature commonly observed following intra-muscular injection of a vaccine (Greaves, 2013) in this strain and age of mouse, and was considered non-adverse.

The small number of protocol-required tissues that could not be examined were spread throughout the treatment groups and therefore considered not to have impacted the quality or integrity of the study.

The remaining histopathology findings were considered unrelated to administration of AZD1222.

Recovery Animals

There were no histopathology findings considered related to the administration of AZD1222.

There were no findings in the administration sites or sciatic nerves in the recovery animals, indicating complete recovery of the AZD1222 related inflammation.

8. CONCLUSION

In conclusion, administration of AZD1222 to CD-1 mice (total viral particle dose of $3.7x10^{10}$) by intramuscular injection on 3 occasions (once every 3 weeks) over a 43 day period was well tolerated, with a transiently higher body temperature in males, decreases in monocytes in males and females (consistent with the expected pharmacology of AZD1222) and increase in globulin and decrease in albumin and albumin/globulin ratio, consistent with an acute phase response, observed.

In all animals dosed with AZD1222, antibodies against the S-glycoprotein were raised and maintained throughout the dosing and recovery periods in all animals.

In AZD1222 animals, higher spleen weights were observed but with no correlating macroscopic or microscopic changes. Non adverse, fully reversible, mixed and/or mononuclear cell inflammation was observed in the subcutaneous tissues and skeletal muscle of the administration sites and adjacent sciatic nerve of animals dosed with AZD1222 which were consistent with the anticipated findings after intra-muscular injection of vaccines.

9. REFERENCES

Greaves (2013). Greaves P, Chouinard L, Ernst H, Mecklenburg L, Pruimboom-Brees I, Rinke M et al. Proliferative and non-proliferative lesions of the rat and mouse soft tissue, skeletal muscle and mesothelium. J Toxicol Pathol 2013; 26 (3 Suppl): 1S–26S.

Sellers (2019). Scientific and Regulatory Policy Committee Points to Consider: Approaches to the Conduct and Interpretation of Vaccine Safety Studies for Clinical and Anatomic Pathologists. Toxicologic Pathology 2020, Vol. 48(2) 257-276.

Figure 1

Summary of group mean body weights: pretreatment and dosing period

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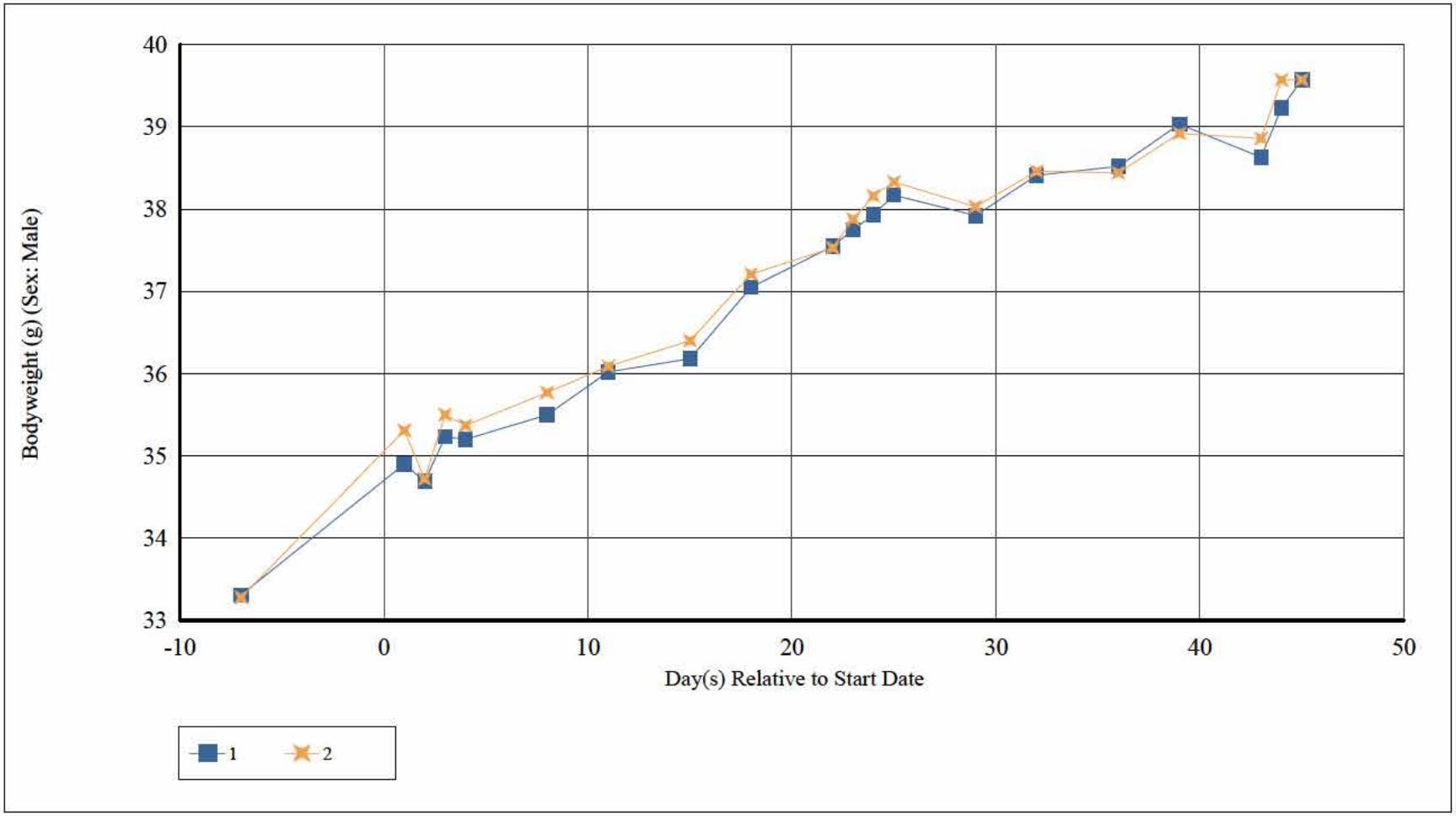

Figure 1

Summary of group mean body weights: pretreatment and dosing period

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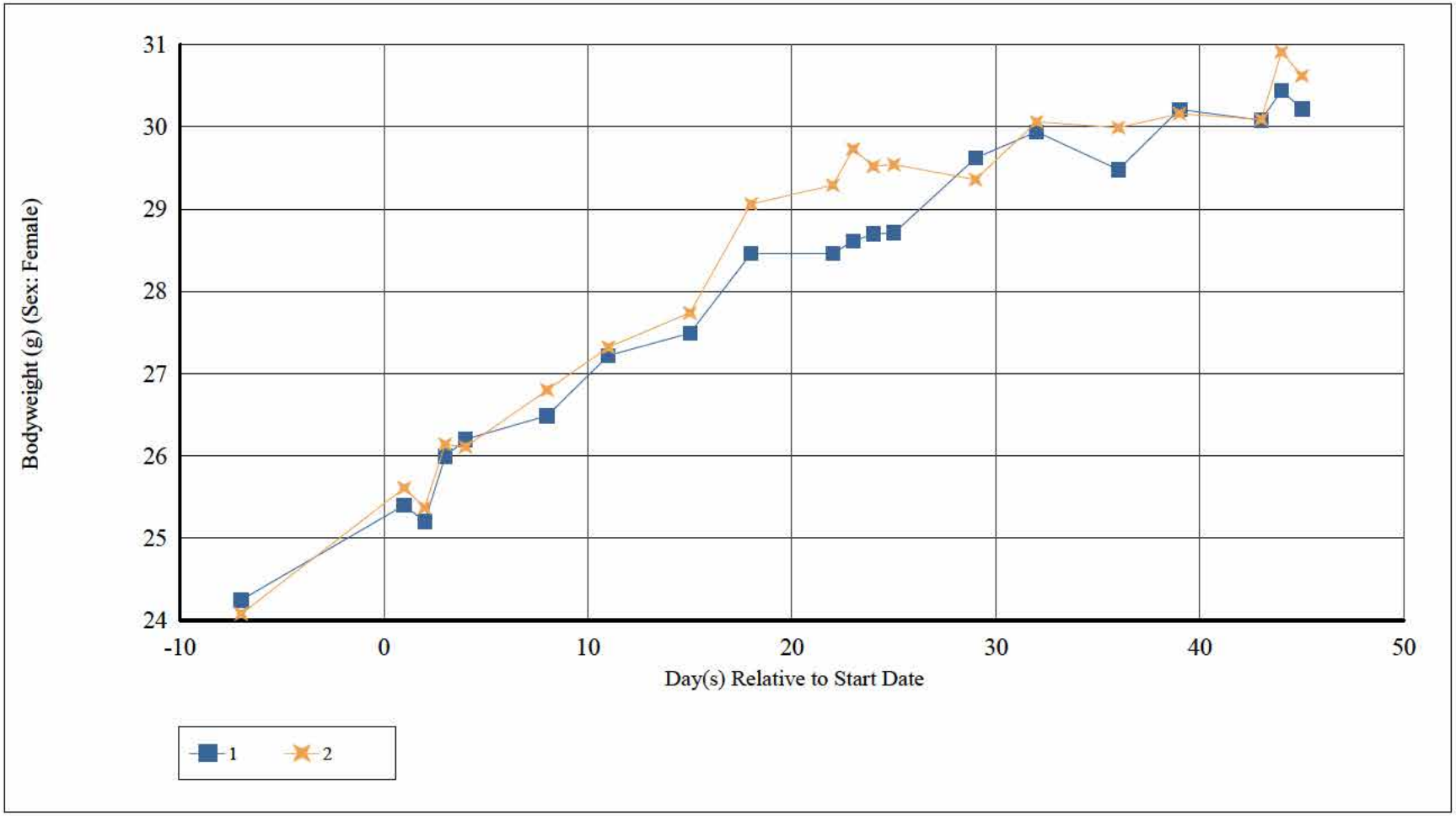


Figure 1

Summary of group mean body weights: recovery period

513351

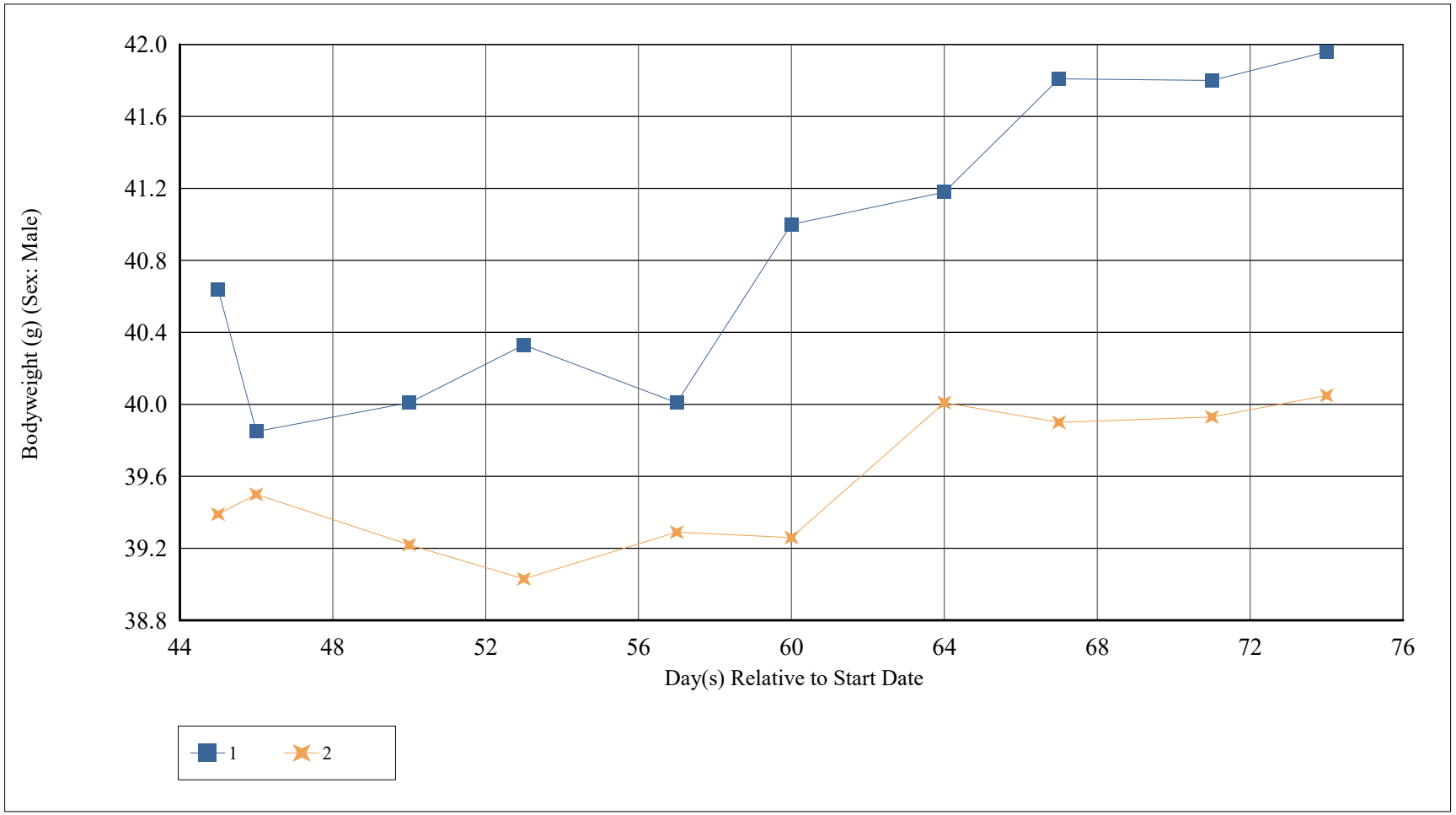


Figure 1

Summary of group mean body weights: recovery period

513351

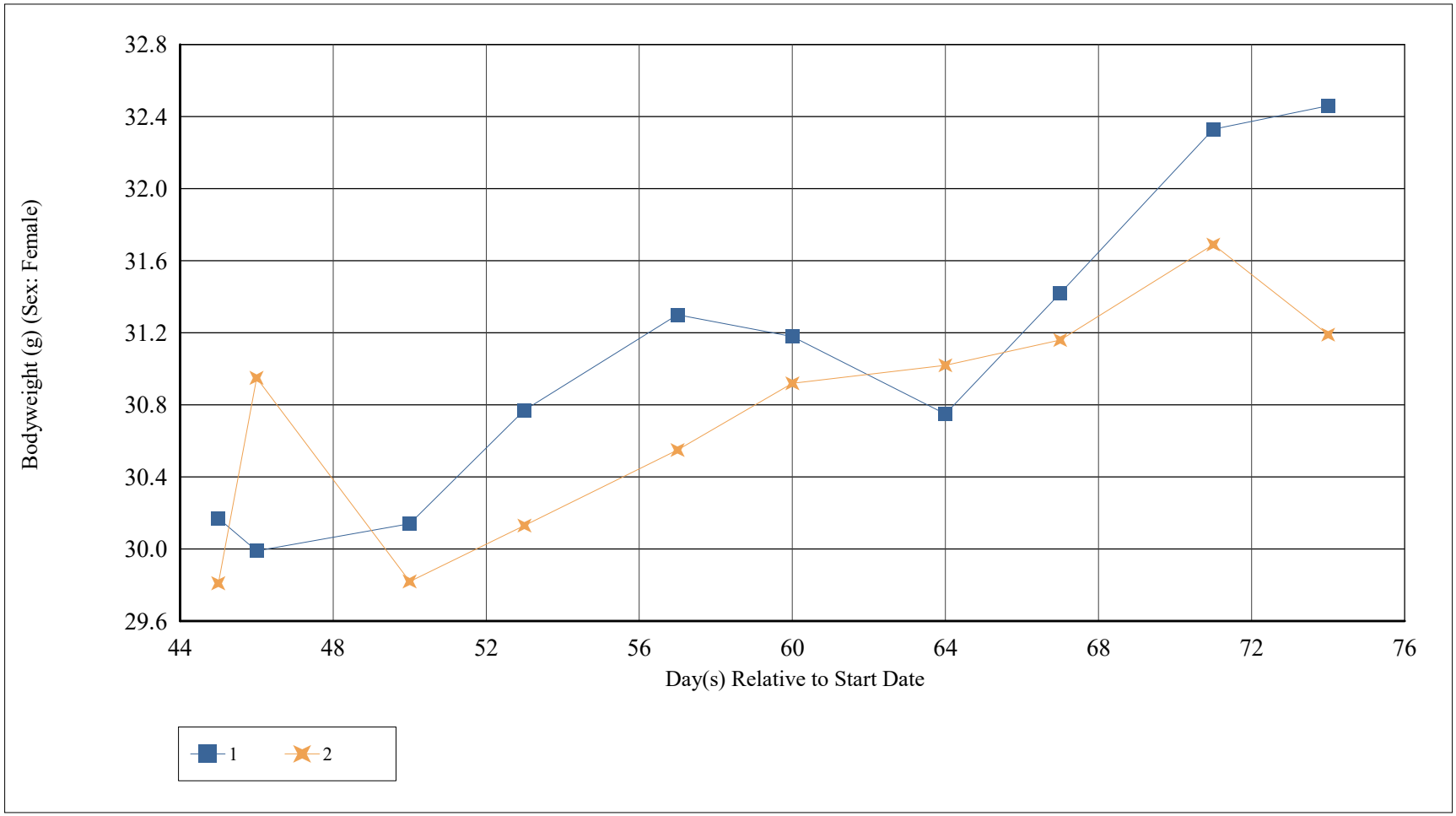
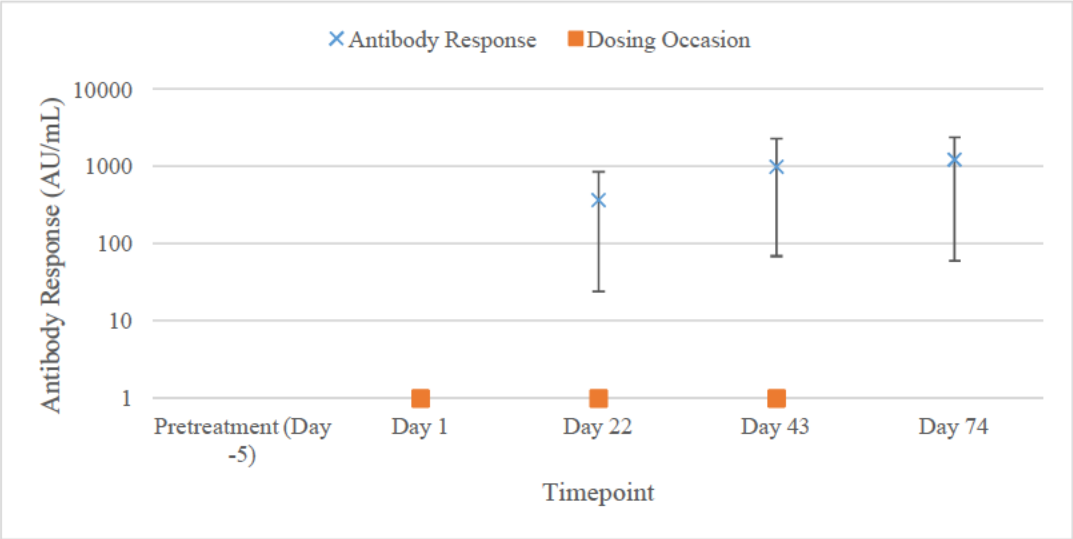


Figure 2

Mean antibody response – Group 2 males

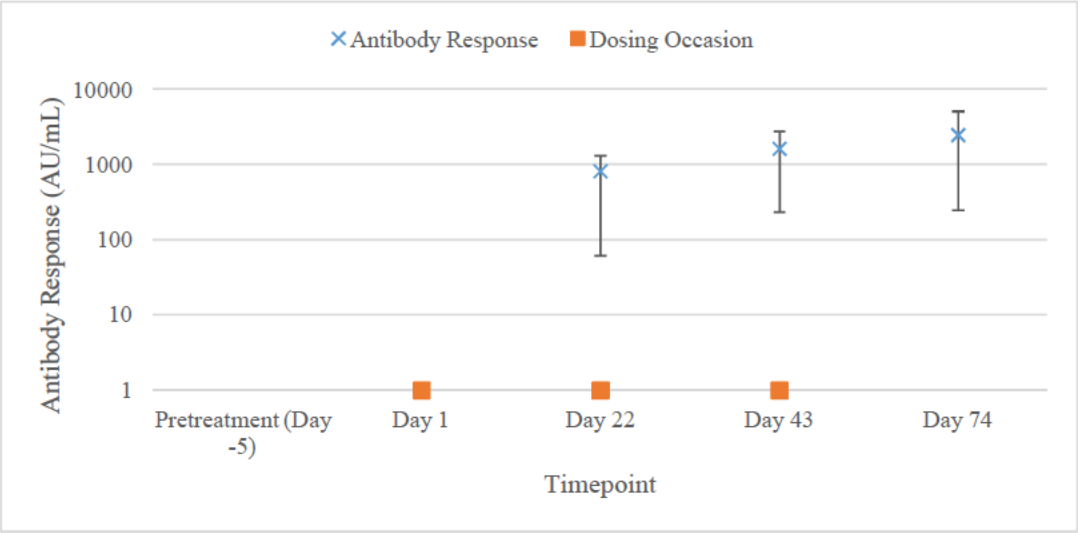


Error bars indicate maximum and minimum antibody concentrations observed at each timepoint.

All samples collected prior to immunisation (Pretreatment; Day -5) were below the limit of quantification for the assay (BLQ; 0.250 AU/mL) and considered seronegative.

Figure 3

Mean antibody response – Group 2 females

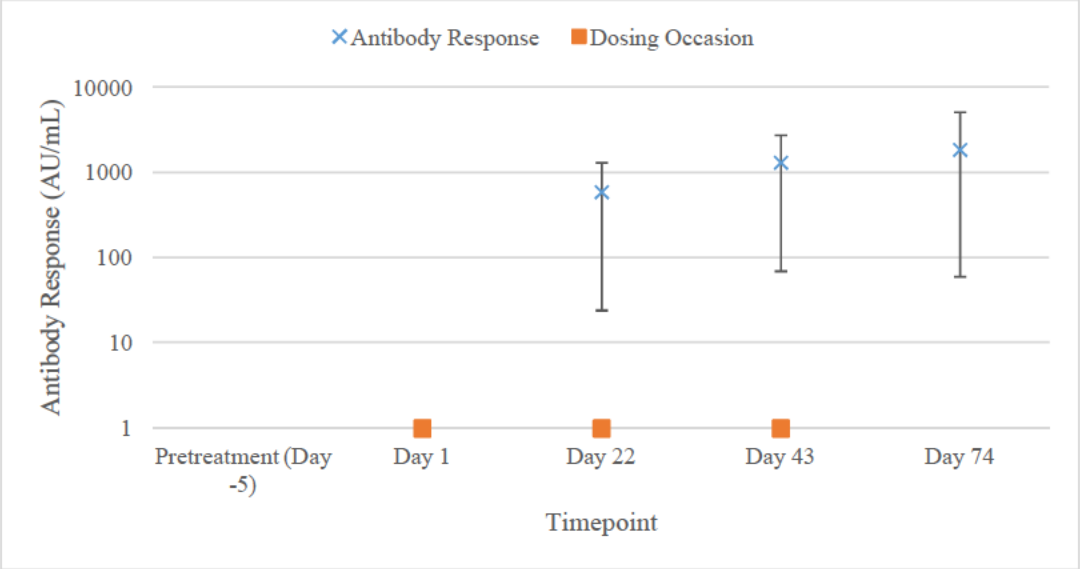


Error bars indicate maximum and minimum antibody concentrations observed at each timepoint.

All samples collected prior to immunisation (Pretreatment; Day -5) were below the limit of quantification for the assay (BLQ; 0.250 AU/mL) and considered seronegative.

Figure 4

Mean antibody response – Group 2



Error bars indicate maximum and minimum antibody concentrations observed at each timepoint.

All samples collected prior to immunisation (Pretreatment; Day -5) were below the limit of quantification for the assay (BLQ; 0.250 AU/mL) and considered seronegative.

Table 1

Summary of clinical observations: pretreatment and dosing period

513351

Observation Type: All Types From Day -7 (Start Date) to 45 (Start Date)	Male 70 ul Group 1	Male 70 ul Group 2	Female 70 ul Group 1	Female 70 ul Group 2
Whiskers Missing				
Number of Animals Affected	0	0	2	0
Number of Times Recorded	0	0	3	0
First to Last seen	-	-	36 - 43	-
Tail, Bent (PT)				
Number of Animals Affected	0	1	0	0
Number of Times Recorded	0	6	0	0
First to Last seen	-	8 - 43	-	-
Hunched Posture				
Number of Animals Affected	1	2	0	0
Number of Times Recorded	1	2	0	0
First to Last seen	15 - 15	15 - 15	-	-
Fur, Ungroomed				
Number of Animals Affected	0	0	1	0
Number of Times Recorded	0	0	1	0
First to Last seen	-	-	36 - 36	-
Fur, Erected				
Number of Animals Affected	40	40	0	36
Number of Times Recorded	1783	1912	0	120
First to Last seen	2 - 45	2 - 45	-	2 - 25
Fur, Thin Cover, Cranium				
Number of Animals Affected	0	0	1	0
Number of Times Recorded	0	0	2	0
First to Last seen	-	-	36 - 43	-
Fur, Thin Cover, Dorsal Cervical				
Number of Animals Affected	0	1	1	4

Table 1

Summary of clinical observations: pretreatment and dosing period

513351

Observation Type: All Types From Day -7 (Start Date) to 45 (Start Date)	Male 70 ul Group 1	Male 70 ul Group 2	Female 70 ul Group 1	Female 70 ul Group 2
Fur, Thin Cover, Dorsal Cervical (Continued...)				
Number of Times Recorded	0	2	2	18
First to Last seen	-	1 - 8	36 - 43	1 - 43
Fur, Thin Cover, Dorsal Thoracic				
Number of Animals Affected	0	0	1	0
Number of Times Recorded	0	0	2	0
First to Last seen	-	-	36 - 43	-
Fur, Thin Cover, Muzzle				
Number of Animals Affected	0	0	1	0
Number of Times Recorded	0	0	2	0
First to Last seen	-	-	36 - 43	-
Skin, Discolored, Pinna, Left, Pale				
Number of Animals Affected	5	0	0	0
Number of Times Recorded	5	0	0	0
First to Last seen	22 - 22	-	-	-
Skin, Discolored, Pinna, Right, Pale				
Number of Animals Affected	5	0	0	0
Number of Times Recorded	5	0	0	0
First to Last seen	22 - 22	-	-	-
Skin, Scab, Dorsal Cervical				
Number of Animals Affected	0	2	0	1
Number of Times Recorded	0	3	0	1
First to Last seen	-	1 - 8	-	43 - 43
Skin, Scab, Dorsal Thoracic				
Number of Animals Affected	1	1	0	0
Number of Times Recorded	3	1	0	0

Table 1

Summary of clinical observations: pretreatment and dosing period

513351

Observation Type: All Types From Day -7 (Start Date) to 45 (Start Date)	Male 70 ul Group 1	Male 70 ul Group 2	Female 70 ul Group 1	Female 70 ul Group 2
Skin, Scab, Dorsal Thoracic (Continued...)				
First to Last seen	1 - 15	8 - 8	-	-
Skin, Scab, Hindlimb, Left				
Number of Animals Affected	1	0	0	0
Number of Times Recorded	1	0	0	0
First to Last seen	1 - 1	-	-	-
Eyeball, Opacity, Right				
Number of Animals Affected	1	0	0	0
Number of Times Recorded	4	0	0	0
First to Last seen	22 - 43	-	-	-
Eyeball, Protruding, Left				
Number of Animals Affected	1	1	0	0
Number of Times Recorded	1	5	0	0
First to Last seen	15 - 15	15 - 43	-	-
Eyeball, Protruding, Right				
Number of Animals Affected	1	1	0	0
Number of Times Recorded	1	5	0	0
First to Last seen	15 - 15	15 - 43	-	-
Repetitive Behavior, Severity Not Recorded				
Number of Animals Affected	1	1	2	0
Number of Times Recorded	3	5	8	0
First to Last seen	15 - 29	15 - 43	15 - 43	-
Activity Increased				
Number of Animals Affected	4	3	4	1
Number of Times Recorded	9	11	8	1
First to Last seen	15 - 43	15 - 43	15 - 43	15 - 15

Table 1

Summary of clinical observations: recovery period

513351

Observation Type: All Types From Day 45 (Start Date) to 74 (Start Date)	Male 70 ul Group 1	Male 70 ul Group 2	Female 70 ul Group 1	Female 70 ul Group 2
Hunched Posture				
Number of Animals Affected	0	0	0	1
Number of Times Recorded	0	0	0	1
First to Last seen	-	-	-	54 - 54
Fur, Ungroomed				
Number of Animals Affected	0	1	0	0
Number of Times Recorded	0	4	0	0
First to Last seen	-	50 - 71	-	-
Fur, Erected				
Number of Animals Affected	19	18	0	1
Number of Times Recorded	112	322	0	1
First to Last seen	45 - 71	45 - 74	-	54 - 54
Fur, Staining, Eyelid, Left, Color Not Recorded				
Number of Animals Affected	0	0	0	1
Number of Times Recorded	0	0	0	1
First to Last seen	-	-	-	54 - 54
Fur, Staining, Eyelid, Right, Color Not Recorded				
Number of Animals Affected	0	0	0	1
Number of Times Recorded	0	0	0	1
First to Last seen	-	-	-	54 - 54
Fur, Thin Cover, Dorsal Thoracic				
Number of Animals Affected	0	0	0	2
Number of Times Recorded	0	0	0	3
First to Last seen	-	-	-	64 - 71
Eye Closed, Left, Partly				
Number of Animals Affected	0	0	0	1

Table 1

Summary of clinical observations: recovery period

513351

Observation Type: All Types	Male		Female	
From Day 45 (Start Date) to 74 (Start Date)	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
Eye Closed, Left, Partly (Continued...)				
Number of Times Recorded	0	0	0	1
First to Last seen	-	-	-	54 - 54
Eye Closed, Right, Partly				
Number of Animals Affected	0	0	0	1
Number of Times Recorded	0	0	0	1
First to Last seen	-	-	-	54 - 54
Repetitive Behavior, Severity Not Recorded				
Number of Animals Affected	0	1	0	0
Number of Times Recorded	0	2	0	0
First to Last seen	-	50 - 57	-	-
Activity Increased				
Number of Animals Affected	2	4	0	0
Number of Times Recorded	8	10	0	0
First to Last seen	50 - 71	50 - 71	-	-

Table 2

Summary of body temperatures

513351

Body Temperature (oC)

Sex: Male		Day(s) Relative to Start Date					
		-7 (DE)	1	2 (CAM)	21	22 (4H)	23
70	Mean	37.12	37.14	37.92	36.93	36.98	38.52
ul	SD	0.62	0.75	0.68	0.75	0.75	0.70
	N	10	10	10	10	10	10
Group 1		-	-	-	-	-	-
70	Mean	36.73	37.61	38.16	37.23	38.25**	38.77
ul	SD	0.56	0.90	1.12	0.72	1.12	0.91
	N	10	10	10	10	10	10
Group 2	%Diff	-1.05	1.27	0.63	0.81	3.43	0.65

Anova & Dunnett: ** = $p \leq 0.01$

Table 2

Summary of body temperatures

513351

Body Temperature (oC)

Sex: Female		Day(s) Relative to Start Date					
		-7 (DE)	1	2 (CAM)	21	22 (4H)	23
70	Mean	37.37	37.54	38.16	37.45	37.00	37.78
ul	SD	0.29	0.42	0.46	0.32	0.41	0.68
	N	10	10	10	10	10	10
Group 1		-	-	-	-	-	-
70	Mean	37.19	37.85	37.66*	37.25	37.32	38.22
ul	SD	0.53	0.44	0.41	0.44	0.28	0.51
	N	10	10	10	10	10	10
Group 2	%Diff	-0.48	0.83	-1.31	-0.53	0.86	1.16

Anova & Dunnett: * = $p \leq 0.05$

Table 3

Summary of body weights: pretreatment and dosing period

513351

Bodyweight (g)

Sex: Male		Day(s) Relative to Start Date						
		-7	1	2	3	4	8	11
70	Mean	33.31	34.90	34.69	35.23	35.20	35.50	36.02
ul	SD	1.80	1.94	1.98	2.20	2.19	2.23	2.36
	N	40	40	40	40	40	40	40
Group 1		-	-	-	-	-	-	-
70	Mean	33.28	35.31	34.72	35.50	35.37	35.77	36.09
ul	SD	1.42	1.65	1.77	1.73	1.61	1.66	1.71
	N	40	40	40	40	40	40	40
Group 2	%Diff	-0.09	1.17	0.08	0.78	0.48	0.75	0.20

Anova & Dunnett

Table 3

Summary of body weights: pretreatment and dosing period

513351

Bodyweight (g)

Sex: Male		Day(s) Relative to Start Date						
		15	18	22	23	24	25	29
70	Mean	36.18	37.05	37.55	37.75	37.93	38.17	37.92
ul	SD	2.38	2.64	2.32	2.54	2.49	2.67	2.60
	N	40	40	40	40	40	40	40
Group 1		-	-	-	-	-	-	-
70	Mean	36.40	37.21	37.53	37.88	38.16	38.33	38.03
ul	SD	1.79	1.74	1.92	1.86	1.90	1.86	1.81
	N	40	40	40	40	40	40	40
Group 2	%Diff	0.62	0.42	-0.07	0.34	0.61	0.42	0.30

Anova & Dunnett

Table 3

Summary of body weights: pretreatment and dosing period

513351

Bodyweight (g)

Sex: Male		Day(s) Relative to Start Date					
		32	36	39	43	44	45
70	Mean	38.41	38.52	39.03	38.63	39.23	39.57
ul	SD	2.59	2.47	2.63	2.39	2.68	2.72
	N	40	40	40	40	40	40
Group 1		-	-	-	-	-	-
70	Mean	38.46	38.44	38.92	38.86	39.57	39.57
ul	SD	1.84	1.93	2.07	2.06	2.10	2.05
	N	40	40	40	40	40	40
Group 2	%Diff	0.14	-0.21	-0.27	0.59	0.87	-0.01

Anova & Dunnett

Table 3

Summary of body weights: pretreatment and dosing period

513351

Bodyweight (g)

Sex: Female		Day(s) Relative to Start Date						
		-7	1	2	3	4	8	11
70	Mean	24.25	25.40	25.20	25.99	26.20	26.49	27.22
ul	SD	1.37	1.81	1.67	1.73	1.85	1.86	1.94
	N	40	40	40	40	40	40	40
Group 1		-	-	-	-	-	-	-
70	Mean	24.08	25.61	25.37	26.14	26.11	26.80	27.32
ul	SD	1.47	2.01	1.97	1.78	1.75	1.93	2.14
	N	40	40	40	40	40	40	40
Group 2	%Diff	-0.69	0.83	0.65	0.56	-0.37	1.17	0.37

Anova & Dunnett

Table 3

Summary of body weights: pretreatment and dosing period

513351

Bodyweight (g)

Sex: Female		Day(s) Relative to Start Date						
		15	18	22	23	24	25	29
70	Mean	27.49	28.46	28.46	28.61	28.70	28.71	29.62
ul	SD	2.12	2.22	1.94	2.12	2.25	2.13	2.43
	N	40	40	40	40	40	40	40
Group 1		-	-	-	-	-	-	-
70	Mean	27.74	29.06	29.29	29.73*	29.52	29.54	29.36
ul	SD	2.39	2.68	2.52	2.38	2.39	2.43	2.38
	N	40	40	40	40	40	40	40
Group 2	%Diff	0.92	2.13	2.92	3.92	2.87	2.89	-0.87

Anova & Dunnett: * = $p \leq 0.05$

Table 3

Summary of body weights: pretreatment and dosing period

513351

Bodyweight (g)

Sex: Female		Day(s) Relative to Start Date					
		32	36	39	43	44	45
70	Mean	29.94	29.48	30.21	30.08	30.44	30.22
ul	SD	2.83	2.40	2.63	2.56	2.43	2.50
	N	40	40	39	39	39	39
Group 1		-	-	-	-	-	-
70	Mean	30.06	29.99	30.16	30.09	30.91	30.62
ul	SD	2.68	2.92	2.79	2.94	3.01	3.25
	N	40	40	40	40	40	40
Group 2	%Diff	0.40	1.73	-0.15	0.03	1.53	1.32

Anova & Dunnett

Table 3

Summary of body weights: recovery period

513351

Bodyweight (g)

Sex: Male		Day(s) Relative to Start Date						
		45	46	50	53	57	60	64
70	Mean	40.64	39.85	40.01	40.33	40.01	41.00	41.18
ul	SD	2.94	2.92	2.71	3.09	2.67	3.04	2.89
	N	20	20	20	20	20	20	20
Group 1		-	-	-	-	-	-	-
70	Mean	39.39	39.50	39.22	39.03	39.29	39.26*	40.01
ul	SD	1.67	1.80	1.60	1.78	1.75	1.65	1.68
	N	20	20	20	20	20	20	20
Group 2	%Diff	-3.06	-0.87	-1.97	-3.24	-1.81	-4.24	-2.84

Anova & Dunnett: * = $p \leq 0.05$

Table 3

Summary of body weights: recovery period

513351

Bodyweight (g)

Sex: Male		Day(s) Relative to Start Date		
		67	71	74
70	Mean	41.81	41.80	41.96
ul	SD	3.32	3.19	3.36
	N	20	20	20
Group 1		-	-	-
70	Mean	39.90*	39.93*	40.05*
ul	SD	2.17	1.84	2.08
	N	20	20	20
Group 2	%Diff	-4.56	-4.47	-4.54

Anova & Dunnett: * = $p \leq 0.05$

Table 3

Summary of body weights: recovery period

513351

Bodyweight (g)

Sex: Female		Day(s) Relative to Start Date						
		45	46	50	53	57	60	64
70	Mean	30.17	29.99	30.14	30.77	31.30	31.18	30.75
ul	SD	2.60	2.51	2.58	2.19	2.54	3.13	2.65
	N	19	19	19	19	19	19	19
Group 1		-	-	-	-	-	-	-
70	Mean	29.81	30.95	29.82	30.13	30.55	30.92	31.02
ul	SD	3.68	3.70	3.38	2.97	3.90	3.78	3.39
	N	20	20	20	20	20	20	20
Group 2	%Diff	-1.22	3.17	-1.07	-2.07	-2.40	-0.85	0.89

Anova & Dunnett

Table 3

Summary of body weights: recovery period

513351

Bodyweight (g)

Sex: Female		Day(s) Relative to Start Date		
		67	71	74
70	Mean	31.42	32.33	32.46
ul	SD	2.96	3.49	3.84
	N	19	19	19
Group 1		-	-	-
70	Mean	31.16	31.69	31.19
ul	SD	3.74	3.82	3.71
	N	20	20	20
Group 2	%Diff	-0.85	-1.98	-3.92

Anova & Dunnett

Table 4

Summary of body weight gains (g): pretreatment and dosing period

513351

Bodyweight Gain (Interval)

Sex: Male		Day(s) Relative to Start Date
		1 → 45
70	Mean	4.67
ul	SD	1.47
	N	40
Group 1		-
70	Mean	4.26
ul	SD	1.24
	N	40
Group 2		-

Anova & Dunnett

Table 4

Summary of body weight gains (g): pretreatment and dosing period

513351

Bodyweight Gain (Interval)

Sex: Female		Day(s) Relative to Start Date
		1 → 45
70	Mean	4.79
ul	SD	1.95
	N	39
Group 1		-
70	Mean	5.02
ul	SD	2.37
	N	40
Group 2		-

Anova & Dunnett

Table 4

Summary of body weight gains (g): recovery period

513351

Bodyweight Gain (Interval)

Sex: Male		Day(s) Relative to Start Date
		45 → 74
70	Mean	1.32
ul	SD	1.66
	N	20
Group 1		-
70	Mean	0.66
ul	SD	1.52
	N	20
Group 2		-

Anova & Dunnett

Table 4

Summary of body weight gains (g): recovery period

513351

Bodyweight Gain (Interval)

Sex: Female		Day(s) Relative to Start Date
		45 → 74
70 ul Group 1	Mean	2.29
	SD	2.21
	N	19
		-
70 ul Group 2	Mean	1.39
	SD	1.45
	N	20
		-

Anova & Dunnett

Table 5

Summary of food consumption: pretreatment and dosing period

513351

Daily Food Cons Per Animal (g)

Sex: Male		Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
70	Mean	5.8	5.2	6.8	6.1	6.5	6.3	7.0
ul	SD	0.5	0.9	1.0	0.5	0.8	0.7	1.3
	N	40	40	40	40	40	39	40
Group 1		-	-	-	-	-	-	-
70	Mean	5.9	4.9	6.5	6.2	6.4	6.1	6.1***
ul	SD	0.4	0.8	0.6	0.5	0.5	0.5	0.7
	N	40	40	40	40	40	40	40
Group 2	%Diff	2.7	-4.4	-3.4	1.8	-1.4	-2.8	-12.9

Anova & Dunnett: *** = $p \leq 0.001$

Table 5

Summary of food consumption: pretreatment and dosing period

513351

Daily Food Cons Per Animal (g)

Sex: Male		Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
70	Mean	6.5	6.5	6.3	6.3	6.5
ul	SD	1.0	0.8	0.7	0.7	1.2
	N	40	40	40	40	40
Group 1		-	-	-	-	-
70	Mean	6.4	6.3	6.2	6.3	6.5
ul	SD	0.6	0.6	0.6	0.5	1.3
	N	40	40	40	40	40
Group 2	%Diff	-2.6	-3.6	-0.8	0.1	1.2

Anova & Dunnett

Table 5

Summary of food consumption: pretreatment and dosing period

513351

Daily Food Cons Per Animal (g)

Sex: Female		Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
70	Mean	4.7	4.6	5.5	5.4	5.7	5.3	6.2
ul	SD	0.3	0.6	0.5	0.4	0.5	0.4	1.4
	N	14	14	14	14	14	13	14
Group 1		-	-	-	-	-	-	-
70	Mean	4.8	3.5***	5.7	5.5	6.1*	5.7	5.5
ul	SD	0.3	0.4	0.5	0.3	0.4	0.8	0.4
	N	14	14	14	14	14	14	14
Group 2	%Diff	0.5	-23.0	2.4	2.2	7.3	8.4	-11.3

Anova & Dunnett: * = $p \leq 0.05$; *** = $p \leq 0.001$

Table 5

Summary of food consumption: pretreatment and dosing period

513351

Daily Food Cons Per Animal (g)

Sex: Female		Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
70	Mean	5.5	5.2	5.6	5.5	6.0
ul	SD	0.5	0.5	0.5	0.3	0.8
	N	14	14	14	14	14
Group 1		-	-	-	-	-
70	Mean	5.7	5.7**	6.0	5.8	6.4
ul	SD	0.4	0.4	0.7	0.7	1.0
	N	14	14	14	14	14
Group 2	%Diff	3.7	9.3	6.8	6.0	6.7

Anova & Dunnett: ** = $p \leq 0.01$

Table 5

Summary of food consumption: recovery period

513351

Daily Food Cons Per Animal (g)

Sex: Male		Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
70	Mean	6.6	6.1	6.6	6.5	7.1	6.5	6.5
ul	SD	0.7	0.5	1.0	1.0	1.2	1.8	0.9
	N	20	20	20	20	20	20	20
Group 1		-	-	-	-	-	-	-
70	Mean	6.6	6.6	6.5	6.9	6.5	7.2	6.6
ul	SD	1.2	1.2	1.3	1.2	1.1	1.2	1.0
	N	20	20	20	20	20	20	20
Group 2	%Diff	-0.8	8.0	-1.0	5.2	-7.3	10.6	0.3

Table 5

Summary of food consumption: recovery period

513351

Daily Food Cons Per Animal (g)

Sex: Female		Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
70	Mean	5.7	5.5	5.6	5.6	5.8	6.1	5.9
ul	SD	0.6	0.4	0.6	0.5	1.3	0.5	0.6
	N	7	7	7	7	7	7	7
Group 1		-	-	-	-	-	-	-
70	Mean	5.8	5.7	5.7	6.0	5.9	6.0	5.7
ul	SD	0.7	0.2	0.6	0.5	0.3	0.6	0.4
	N	7	7	7	7	7	7	7
Group 2	%Diff	2.0	5.0	1.4	8.1	1.2	-2.0	-3.2

Anova & Dunnett

Table 6

Summary of haematology values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Male		Reporting Hematology						
		WBC (10^9/L) [k]	NEUT (10^9/L) [k]	LYMPH (10^9/L) [k]	MONO (10^9/L) [k]	EOS (10^9/L) [k]	BASO (10^9/L) [k]	LUC (10^9/L) [k]
70 ul Group 1	Mean	3.841	0.603	3.034	0.093	0.083	0.008	0.021
	SD	2.116	0.303	1.756	0.054	0.040	0.008	0.022
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
70 ul Group 2	Mean	3.384	0.677	2.563	0.040	0.068	0.007	0.028
	SD	1.681	0.320	1.371	0.038	0.027	0.007	0.019
	N	10	10	10	10	10	10	10
	tCtrl	0.88	1.12	0.84	0.43	0.82	0.88	1.33

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Male		Reporting Hematology						
		RBC (10^12/L) [k]	HGB (g/L) [k]	HCT (L/L) [k]	MCV (fL) [k]	MCH (pg) [k]	MCHC (g/L) [k]	RDW (%) [k]
70 ul Group 1	Mean	10.198	150.7	0.4790	47.05	14.79	314.7	12.97
	SD	0.536	4.8	0.0111	1.64	0.44	4.7	0.51
	N	10	10	10	10	10	10	10
	-		.	-	-	-	-	-
70 ul Group 2	Mean	10.055	147.6	0.4698	46.72	14.69	314.4	12.94
	SD	0.485	6.3	0.0204	1.00	0.36	2.8	0.75
	N	10	10	10	10	10	10	10
	tCtrl	0.99	0.98	0.98	0.99	0.99	1.00	1.00

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Male		Reporting Hematology		
		PLT (10^9/L) [k]	RETIC (10^9/L) [k]	RETIC (%) [k]
70 ul Group 1	Mean	1313.3	312.67	3.07
	SD	142.8	41.39	0.52
	N	10	10	10
		-	-	-
70 ul Group 2	Mean	1239.0	310.62	3.08
	SD	121.2	35.67	0.34
	N	10	10	10
	tCtrl	0.94	0.99	1.00

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: main study animals

513351
Day: 45 Relative to Start Date

Sex: Female		Reporting Hematology						
		WBC (10^9/L) [k]	NEUT (10^9/L) [k]	LYMPH (10^9/L) [k]	MONO (10^9/L) [k]	EOS (10^9/L) [k]	BASO (10^9/L) [k]	LUC (10^9/L) [k]
70	Mean	5.413	0.894	4.205	0.106	0.154	0.014	0.042
ul	SD	2.571	0.490	2.019	0.050	0.094	0.011	0.030
	N	10	10	10	10	10	10	10
Group 1		-	-	-	-	-	-	-
70	Mean	5.046	1.110	3.671	0.041 **	0.141	0.015	0.066
ul	SD	1.993	0.347	1.680	0.015	0.052	0.011	0.040
	N	10	10	10	10	10	10	10
Group 2	tCtrl	0.93	1.24	0.87	0.39	0.92	1.07	1.57

[k] - Kruskal-Wallis & Dunn: ** = $p \leq 0.01$

Table 6

Summary of haematology values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Female		Reporting Hematology						
		RBC (10^12/L) [k]	HGB (g/L) [k]	HCT (L/L) [k]	MCV (fL) [k]	MCH (pg) [k]	MCHC (g/L) [k]	RDW (%) [k]
70 ul Group 1	Mean	9.903	149.7	0.4705	47.56	15.12	318.2	12.98
	SD	0.579	7.5	0.0237	1.20	0.42	4.7	0.40
	N	10	10	10	10	10	10	10
		-	.	-	-	-	-	-
70 ul Group 2	Mean	9.852	149.1	0.4716	47.91	15.18	316.8	13.22
	SD	0.566	5.2	0.0219	1.92	0.63	6.4	0.45
	N	10	10	10	10	10	10	10
	tCtrl	0.99	1.00	1.00	1.01	1.00	1.00	1.02

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Female		Reporting Hematology		
		PLT (10^9/L) [k]	RETIC (10^9/L) [k]	RETIC (%) [k]
70 ul Group 1	Mean	1148.5	318.75	3.21
	SD	108.7	96.05	0.94
	N	10	10	10
		-	-	-
70 ul Group 2	Mean	1130.6	333.53	3.41
	SD	104.1	86.48	0.98
	N	10	10	10
	tCtrl	0.98	1.05	1.06

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Male		Reporting Hematology						
		WBC (10^9/L) [k]	NEUT (10^9/L) [k]	LYMPH (10^9/L) [k]	MONO (10^9/L) [k]	EOS (10^9/L) [k]	BASO (10^9/L) [k]	LUC (10^9/L) [k]
70	Mean	2.034	0.217	1.709	0.031	0.063	0.003	0.010
ul	SD	1.305	0.107	1.189	0.020	0.043	0.005	0.015
	N	7	7	7	7	7	7	7
Group 1		-	-	-	-	-	-	-
70	Mean	3.383	0.599	2.554	0.076	0.131	0.007	0.014
ul	SD	2.150	0.514	1.636	0.063	0.123	0.005	0.016
	N	7	7	7	7	7	7	7
Group 2	tCtrl	1.66	2.76	1.49	2.41	2.09	2.50	1.43

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Male		Reporting Hematology						
		RBC (10^12/L) [k]	HGB (g/L) [k]	HCT (L/L) [k]	MCV (fL) [k]	MCH (pg) [k]	MCHC (g/L) [k]	RDW (%) [k]
70 ul Group 1	Mean	9.460	138.6	0.4566	48.30	14.64	303.9	12.74
	SD	0.478	6.0	0.0217	1.57	0.39	4.7	0.66
	N	7	7	7	7	7	7	7
	-		.	-	-	-	-	-
70 ul Group 2	Mean	10.127 *	149.4 *	0.4874 *	48.17	14.79	306.7	12.94
	SD	0.425	5.1	0.0167	1.32	0.32	7.3	0.66
	N	7	7	7	7	7	7	7
	tCtrl	1.07	1.08	1.07	1.00	1.01	1.01	1.02

[k] - Kruskal-Wallis & Dunn: * = $p \leq 0.05$

Table 6

Summary of haematology values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Male		Reporting Hematology		
		PLT (10^9/L) [k]	RETIC (10^9/L) [k]	RETIC (%) [k]
70 ul Group 1	Mean	1084.6	321.99	3.41
	SD	182.0	23.51	0.26
	N	7	7	7
		-	-	-
70 ul Group 2	Mean	1206.0	318.09	3.14
	SD	194.7	23.70	0.19
	N	7	7	7
	tCtrl	1.11	0.99	0.92

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Female		Reporting Hematology						
		WBC (10^9/L) [k]	NEUT (10^9/L) [k]	LYMPH (10^9/L) [k]	MONO (10^9/L) [k]	EOS (10^9/L) [k]	BASO (10^9/L) [k]	LUC (10^9/L) [k]
70	Mean	5.054	0.552	4.184	0.066	0.211	0.012	0.026
ul	SD	1.473	0.125	1.295	0.055	0.156	0.004	0.016
	N	9	9	9	9	9	9	9
Group 1		-	-	-	-	-	-	-
70	Mean	4.934	0.584	4.103	0.070	0.131	0.011	0.033
ul	SD	1.198	0.132	1.167	0.057	0.047	0.004	0.014
	N	7	7	7	7	7	7	7
Group 2	tCtrl	0.98	1.06	0.98	1.07	0.62	0.94	1.29

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Female		Reporting Hematology						
		RBC (10^12/L) [k]	HGB (g/L) [k]	HCT (L/L) [k]	MCV (fL) [k]	MCH (pg) [k]	MCHC (g/L) [k]	RDW (%) [k]
70 ul Group 1	Mean	10.073	154.0	0.4878	48.49	15.30	315.4	13.30
	SD	0.394	3.4	0.0086	1.23	0.48	5.9	0.73
	N	9	9	9	9	9	9	9
		-	.	-	-	-	-	-
70 ul Group 2	Mean	9.871	150.3	0.4824	48.94	15.20	311.0	13.43
	SD	0.538	7.8	0.0216	0.85	0.36	4.0	0.71
	N	7	7	7	7	7	7	7
	tCtrl	0.98	0.98	0.99	1.01	0.99	0.99	1.01

[k] - Kruskal-Wallis & Dunn

Table 6

Summary of haematology values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Female		Reporting Hematology		
		PLT (10^9/L) [k]	RETIC (10^9/L) [k]	RETIC (%) [k]
70 ul Group 1	Mean	1125.6	373.19	3.70
	SD	123.1	128.12	1.20
	N	9	9	9
		-	-	-
70 ul Group 2	Mean	975.3	359.56	3.61
	SD	134.9	82.60	0.73
	N	7	7	7
	tCtrl	0.87	0.96	0.98

[k] - Kruskal-Wallis & Dunn

Table 7

Summary of plasma chemistry values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Male		Reporting Biochemistry						
		AST (U/L) [k]	ALT (U/L) [k]	ALP (U/L) [k]	GLDH (U/L) [k]	TBIL (umol/L) [k]	BILEAC (umol/L) [k]	UREA (mmol/L) [k]
70	Mean	72.2	64.2	64.1	29.08	1.44	2.90	6.96
ul	SD	24.1	15.5	9.6	22.38	0.59	1.16	1.05
	N	10	10	10	10	10	10	10
Group 1		-	-	-	-	-	-	-
70	Mean	80.8	61.1	58.6	41.91	1.25	1.91	7.38
ul	SD	25.6	18.6	14.2	44.55	0.00	0.82	1.19
	N	10	10	10	10	10	10	10
Group 2	tCtrl	1.12	0.95	0.91	1.44	0.87	0.66	1.06

[k] - Kruskal-Wallis & Dunn

Table 7

Summary of plasma chemistry values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Male		Reporting Biochemistry						
		CREAT (umol/L) [k]	GLUC (mmol/L) [k]	CHOL (mmol/L) [k]	TRIG (mmol/L) [k]	TPROT (g/L) [k]	ALB (g/L) [k]	GLOB (g/L) [k]
70	Mean	8.0	10.312	3.328	1.393	49.19	31.29	17.90
ul	SD	0.0	1.456	0.512	0.554	1.87	1.62	0.99
	N	10	10	10	10	10	10	10
Group 1		-	-	-	-	-	-	-
70	Mean	8.0	9.976	3.526	1.828	50.74	29.36 *	21.38 ***
ul	SD	0.0	1.149	0.316	0.681	2.07	2.25	1.34
	N	10	10	10	10	10	10	10
Group 2	tCtrl	1.00	0.97	1.06	1.31	1.03	0.94	1.19

[k] - Kruskal-Wallis & Dunn: * = $p \leq 0.05$; *** = $p \leq 0.001$

Table 7

Summary of plasma chemistry values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Male		Reporting Biochemistry					
		A/G (ratio) [k]	CA (mmol/L) [k]	NA (mmol/L) [k]	K (mmol/L) [k]	CL (mmol/L) [k]	PHOS (mmol/L) [k]
70	Mean	1.77	2.405	150.9	4.79	108.1	1.990
ul	SD	0.13	0.121	1.4	0.53	2.1	0.248
	N	10	10	10	10	10	10
Group 1		-	-	-	-	-	-
70	Mean	1.39 ***	2.445	151.3	4.61	108.4	1.876
ul	SD	0.18	0.078	2.5	0.34	2.3	0.343
	N	10	10	10	10	10	10
Group 2	tCtrl	0.79	1.02	1.00	0.96	1.00	0.94

[k] - Kruskal-Wallis & Dunn: *** = $p \leq 0.001$

Table 7

Summary of plasma chemistry values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Female		Reporting Biochemistry						
		AST (U/L) [k]	ALT (U/L) [k]	ALP (U/L) [k]	GLDH (U/L) [k]	TBIL (umol/L) [k]	BILEAC (umol/L) [k]	UREA (mmol/L) [k]
70	Mean	126.2	49.5	99.3	18.17	1.25	4.56	6.52
ul	SD	84.2	20.4	19.8	14.99	0.00	2.43	1.50
	N	10	10	10	10	10	10	10
Group 1		-	-	-	-	-	-	-
70	Mean	68.7 **	31.1 *	71.7 **	8.90 *	1.25	3.33	6.05
ul	SD	10.8	4.5	10.9	4.40	0.00	2.05	0.84
	N	10	10	10	10	10	10	10
Group 2	tCtrl	0.54	0.63	0.72	0.49	1.00	0.73	0.93

[k] - Kruskal-Wallis & Dunn: * = $p \leq 0.05$; ** = $p \leq 0.01$

Table 7

Summary of plasma chemistry values: main study animals

513351

Day: 45 Relative to Start Date

Sex: Female		Reporting Biochemistry						
		CREAT (umol/L) [k]	GLUC (mmol/L) [k]	CHOL (mmol/L) [k]	TRIG (mmol/L) [k]	TPROT (g/L) [k]	ALB (g/L) [k]	GLOB (g/L) [k]
70	Mean	8.0	10.939	2.405	2.469	50.11	34.85	15.26
ul	SD	0.0	1.373	0.588	1.110	2.25	1.54	1.98
	N	10	10	10	10	10	10	10
Group 1		-	-	-	-	-	-	-
70	Mean	10.4	11.683	2.110	1.294 **	49.97	31.38 **	18.59 **
ul	SD	3.9	1.585	0.319	0.595	2.73	2.23	1.71
	N	10	10	10	10	10	10	10
Group 2	tCtrl	1.30	1.07	0.88	0.52	1.00	0.90	1.22

[k] - Kruskal-Wallis & Dunn: ** = $p \leq 0.01$

Table 7

Summary of plasma chemistry values: main study animals

513351
Day: 45 Relative to Start Date

Sex: Female		Reporting Biochemistry					
		A/G (ratio) [k]	CA (mmol/L) [k]	NA (mmol/L) [k]	K (mmol/L) [k]	CL (mmol/L) [k]	PHOS (mmol/L) [k]
70	Mean	2.32	2.463	150.8	4.58	109.1	2.027
ul	SD	0.35	0.081	2.0	0.41	2.2	0.531
	N	10	10	10	10	10	10
Group 1		-	-	-	-	-	-
70	Mean	1.68 ***	2.471	147.9 **	4.33	107.1 *	1.852
ul	SD	0.21	0.053	1.2	0.46	1.9	0.389
	N	10	10	10	10	10	10
Group 2	tCtrl	0.72	1.00	0.98	0.95	0.98	0.91

[k] - Kruskal-Wallis & Dunn: * = $p \leq 0.05$; ** = $p \leq 0.01$; *** = $p \leq 0.001$

Table 7

Summary of plasma chemistry values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Male		Reporting Biochemistry						
		AST (U/L) [k]	ALT (U/L) [k]	ALP (U/L) [k]	GLDH (U/L) [k]	TBIL (umol/L) [k]	BILEAC (umol/L) [k]	UREA (mmol/L) [k]
70 ul Group 1	Mean	54.5	57.4	63.6	18.69	2.07	2.21	7.50
	SD	11.0	18.5	25.2	11.20	0.89	0.94	1.68
	N	10	10	10	10	10	9	10
	-	-	-	-	-	-	-	-
70 ul Group 2	Mean	57.8	59.0	55.9	18.44	2.13	3.20	6.57
	SD	16.1	29.6	13.0	8.59	0.98	1.69	1.17
	N	10	10	10	10	10	10	10
	tCtrl	1.06	1.03	0.88	0.99	1.03	1.45	0.88

[k] - Kruskal-Wallis & Dunn

Table 7

Summary of plasma chemistry values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Male		Reporting Biochemistry						
		CREAT (umol/L) [k]	GLUC (mmol/L) [k]	CHOL (mmol/L) [k]	TRIG (mmol/L) [k]	TPROT (g/L) [k]	ALB (g/L) [k]	GLOB (g/L) [k]
70	Mean	8.0	10.689	3.473	2.484	48.62	31.16	17.46
ul	SD	0.0	0.994	0.752	0.848	2.19	1.90	0.87
	N	10	10	10	10	10	10	10
Group 1		-	-	-	-	-	-	-
70	Mean	8.0	10.824	3.183	1.390 **	49.66	31.68	17.98
ul	SD	0.0	2.042	0.523	0.590	2.54	2.01	1.35
	N	10	10	10	10	10	10	10
Group 2	tCtrl	1.00	1.01	0.92	0.56	1.02	1.02	1.03

[k] - Kruskal-Wallis & Dunn: ** = $p \leq 0.01$

Table 7

Summary of plasma chemistry values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Male		Reporting Biochemistry					
		A/G (ratio) [k]	CA (mmol/L) [k]	NA (mmol/L) [k]	K (mmol/L) [k]	CL (mmol/L) [k]	PHOS (mmol/L) [k]
70	Mean	1.79	2.409	149.1	4.56	108.0	1.732
ul	SD	0.12	0.067	1.6	0.27	1.5	0.139
	N	10	10	10	10	10	10
Group 1		-	-	-	-	-	-
70	Mean	1.77	2.445	149.7	4.39	108.1	2.292 **
ul	SD	0.15	0.098	1.9	0.44	1.7	0.496
	N	10	10	10	10	10	10
Group 2	tCtrl	0.99	1.01	1.00	0.96	1.00	1.32

[k] - Kruskal-Wallis & Dunn: ** = $p \leq 0.01$

Table 7

Summary of plasma chemistry values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Female		Reporting Biochemistry						
		AST (U/L) [k]	ALT (U/L) [k]	ALP (U/L) [k]	GLDH (U/L) [k]	TBIL (umol/L) [k]	BILEAC (umol/L) [k]	UREA (mmol/L) [k]
70 ul Group 1	Mean	64.3	39.3	77.8	16.53	1.39	4.83	5.93
	SD	15.6	15.9	12.7	14.05	0.42	3.71	1.07
	N	9	9	9	9	9	8	9
	-	-	-	-	-	-	-	-
70 ul Group 2	Mean	62.3	37.6	78.6	18.16	1.40	4.14	5.74
	SD	14.7	20.8	18.5	16.25	0.45	3.98	0.98
	N	10	10	10	9	9	9	9
	tCtrl	0.97	0.96	1.01	1.10	1.01	0.86	0.97

[k] - Kruskal-Wallis & Dunn

Table 7

Summary of plasma chemistry values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Female		Reporting Biochemistry						
		CREAT (umol/L) [k]	GLUC (mmol/L) [k]	CHOL (mmol/L) [k]	TRIG (mmol/L) [k]	TPROT (g/L) [k]	ALB (g/L) [k]	GLOB (g/L) [k]
70	Mean	8.0	12.178	2.549	1.365	48.14	35.58	12.95
ul	SD	0.0	1.419	0.484	1.117	1.59	1.75	1.23
	N	8	8	9	8	8	9	8
Group 1		-	-	-	-	-	-	-
70	Mean	8.0	12.217	2.380	1.478	49.71	34.55	15.42 *
ul	SD	0.0	1.331	0.763	0.829	2.41	1.44	2.34
	N	9	9	9	9	9	10	9
Group 2	tCtrl	1.00	1.00	0.93	1.08	1.03	0.97	1.19

[k] - Kruskal-Wallis & Dunn: * = $p \leq 0.05$

Table 7

Summary of plasma chemistry values: recovery animals

513351

Day: 74 Relative to Start Date

Sex: Female		Reporting Biochemistry					
		A/G (ratio) [k]	CA (mmol/L) [k]	NA (mmol/L) [k]	K (mmol/L) [k]	CL (mmol/L) [k]	PHOS (mmol/L) [k]
70	Mean	2.75	2.424	146.8	4.16	107.7	2.379
ul	SD	0.29	0.055	2.3	0.36	2.3	0.395
	N	8	9	9	9	9	8
Group 1		-	-	-	-	-	-
70	Mean	2.28 *	2.379	145.8	4.26	107.8	2.219
ul	SD	0.44	0.099	2.6	0.53	2.9	0.320
	N	9	9	10	10	10	9
Group 2	tCtrl	0.83	0.98	0.99	1.03	1.00	0.93

[k] - Kruskal-Wallis & Dunn: * = $p \leq 0.05$

Table 8

Antibody responses – Group 2

Animal No.	Gender	Antibody Concentration (AU/mL)			
		Pretreatment	Day 22	Day 43	Day 74
2201	Male	BLQ	269.436	744.020	1166.157
2202	Male	BLQ	437.818	1029.032	1219.516
2203	Male	BLQ	278.852	829.283	1362.400
2204	Male	BLQ	24.297	69.734	60.586
2205	Male	BLQ	851.620	2297.104	2392.740
Mean of male animals		-	372.405	993.835	1240.280
SD of male animals		-	305.966	812.896	827.750
2701	Female	BLQ	1309.884	2759.980	5115.546
2702	Female	BLQ	358.910	569.779	596.055
2703	Female	BLQ	1243.263	1933.017	2538.552
2704	Female	BLQ	61.889	233.627	247.947
2705	Female	BLQ	1107.705	2684.628	3888.503
Mean of female animals		-	816.330	1636.206	2477.321
SD of female animals		-	567.711	1178.415	2089.539
Overall Mean		-	594.367	1315.020	1858.800
Overall SD		-	489.480	1012.667	1634.049

BLQ = Below Limit of Quantification (0.250 AU/mL)
- = Not applicable

Table 9

Summary of absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Terminal Body Weight (g) [a]	Mean	37.40	39.01 *
	SD	2.28	2.43
	N	20	20
	%Diff	-	4.32
Brain Weight (g) [a]	Mean	0.5101	0.5089
	SD	0.0194	0.0265
	N	20	20
	%Diff	-	-0.2255
Epididymis Weight (g) [a]	Mean	0.1139	0.1184
	SD	0.0135	0.0152
	N	20	20
	%Diff	-	3.9508
Gland, Adrenal Weight (g) [a]	Mean	0.00685	0.00658
	SD	0.00211	0.00167
	N	20	20
	%Diff	-	-4.01460
Gland, Pituitary Weight (g) [a]	Mean	0.00246	0.00268
	SD	0.00067	0.00062
	N	20	20
	%Diff	-	8.94309
Gland, Prostate Weight (g) [a]	Mean	0.0279	0.0335
	SD	0.0175	0.0202
	N	20	20
	%Diff	-	19.8925
Heart Weight (g) [a]	Mean	0.2325	0.2213
	SD	0.0233	0.0194
	N	20	20
	%Diff	-	-4.8387
Kidney Weight (g) [a]	Mean	0.7009	0.7210
	SD	0.0591	0.0561
	N	20	20
	%Diff	-	2.8751

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 9

Summary of absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Liver/Gallbladder Weight (g) [a]	Mean	2.2189	2.4216 **
	SD	0.1378	0.2469
	N	20	20
	%Diff	-	9.1376
Lung Weight (g) [a]	Mean	0.2541	0.2333
	SD	0.0560	0.0208
	N	20	20
	%Diff	-	-8.1677
Spleen Weight (g) [a]	Mean	0.0910	0.1215 ***
	SD	0.0121	0.0203
	N	20	20
	%Diff	-	33.5899
Testis Weight (g) [a]	Mean	0.2671	0.2734
	SD	0.0381	0.0378
	N	20	20
	%Diff	-	2.3778
Thymus Weight (g) [a]	Mean	0.0305	0.0339
	SD	0.0064	0.0080
	N	20	20
	%Diff	-	11.1475

[a] - Anova & Dunnett: ** = $p \leq 0.01$; *** = $p \leq 0.001$

Table 9

Summary of absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Terminal Body Weight (g) [a]	Mean	29.70	30.44
	SD	2.39	2.47
	N	20	20
	%Diff	-	2.49
Brain Weight (g) [a]	Mean	0.5003	0.5018
	SD	0.0354	0.0175
	N	20	20
	%Diff	-	0.2999
Gland, Adrenal Weight (g) [a]	Mean	0.00987	0.01096
	SD	0.00236	0.00262
	N	20	20
	%Diff	-	11.04916
Gland, Pituitary Weight (g) [a]	Mean	0.00308	0.00276
	SD	0.00069	0.00049
	N	20	20
	%Diff	-	-10.24390
Heart Weight (g) [a]	Mean	0.1722	0.1778
	SD	0.0202	0.0132
	N	20	20
	%Diff	-	3.2530
Kidney Weight (g) [a]	Mean	0.4098	0.4338
	SD	0.0359	0.0573
	N	20	20
	%Diff	-	5.8572
Liver/Gallbladder Weight (g) [a]	Mean	1.7609	1.8717
	SD	0.2491	0.3284
	N	20	20
	%Diff	-	6.2953
Lung Weight (g) [a]	Mean	0.2053	0.2147
	SD	0.0197	0.0203
	N	20	20
	%Diff	-	4.5798

[a] - Anova & Dunnett

Table 9

Summary of absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2	
Ovary Weight (g) [a]	Mean	0.0237	0.0261	
	SD	0.0090	0.0054	
	N	20	20	
	%Diff	-	10.3594	
Spleen Weight (g) [a]	Mean	0.1227	0.1738	***
	SD	0.0265	0.0472	
	N	20	20	
	%Diff	-	41.6633	
Thymus Weight (g) [a]	Mean	0.0431	0.0422	
	SD	0.0132	0.0118	
	N	20	20	
	%Diff	-	-1.9744	
Uterus/Cervix/Oviduct (g) [a]	Mean	0.2510	0.2188	
	SD	0.0870	0.0776	
	N	20	20	
	%Diff	-	-12.8312	

[a] - Anova & Dunnett: *** = $p \leq 0.001$

Table 9

Summary of absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Terminal Body Weight (g) [a]	Mean	41.57	39.40 *
	SD	3.70	1.92
	N	20	20
	%Diff	-	-5.22
Brain Weight (g) [a]	Mean	0.5112	0.5161
	SD	0.0237	0.0232
	N	20	20
	%Diff	-	0.9586
Epididymis Weight (g) [a]	Mean	0.1217	0.1170
	SD	0.0167	0.0138
	N	20	20
	%Diff	-	-3.8224
Gland, Adrenal Weight (g) [a]	Mean	0.00572	0.00533
	SD	0.00213	0.00213
	N	20	20
	%Diff	-	-6.90559
Gland, Pituitary Weight (g) [a]	Mean	0.00265	0.00266
	SD	0.00049	0.00074
	N	20	20
	%Diff	-	0.37736
Gland, Prostate Weight (g) [a]	Mean	0.0266	0.0258
	SD	0.0137	0.0157
	N	20	20
	%Diff	-	-3.0075
Heart Weight (g) [a]	Mean	0.2285	0.2364
	SD	0.0231	0.0171
	N	20	20
	%Diff	-	3.4581
Kidney Weight (g) [a]	Mean	0.6954	0.7474
	SD	0.0950	0.1045
	N	20	20
	%Diff	-	7.4854

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 9

Summary of absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Liver/Gallbladder Weight (g) [a]	Mean	2.4456	2.3021
	SD	0.3273	0.1621
	N	20	20
	%Diff	-	-5.8658
Lung Weight (g) [a]	Mean	0.2439	0.2450
	SD	0.0473	0.0264
	N	20	20
	%Diff	-	0.4510
Spleen Weight (g) [a]	Mean	0.1018	0.0989
	SD	0.0186	0.0169
	N	20	20
	%Diff	-	-2.8501
Testis Weight (g) [a]	Mean	0.2669	0.2742
	SD	0.0375	0.0377
	N	20	20
	%Diff	-	2.7351
Thymus Weight (g) [a]	Mean	0.0307	0.0281
	SD	0.0137	0.0092
	N	20	20
	%Diff	-	-8.4691

[a] - Anova & Dunnett

Table 9

Summary of absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Terminal Body Weight (g) [a]	Mean	31.81	30.73
	SD	3.34	3.82
	N	19	20
	%Diff	-	-3.40
Brain Weight (g) [a]	Mean	0.5179	0.5156
	SD	0.0334	0.0301
	N	19	20
	%Diff	-	-0.4527
Gland, Adrenal Weight (g) [a]	Mean	0.01009	0.00907
	SD	0.00595	0.00295
	N	19	20
	%Diff	-	-10.10433
Gland, Pituitary Weight (g) [a]	Mean	0.00345	0.00320
	SD	0.00089	0.00084
	N	19	20
	%Diff	-	-7.46189
Heart Weight (g) [a]	Mean	0.1767	0.1726
	SD	0.0251	0.0199
	N	19	20
	%Diff	-	-2.3407
Kidney Weight (g) [a]	Mean	0.4151	0.4182
	SD	0.0503	0.0647
	N	19	20
	%Diff	-	0.7335
Liver/Gallbladder Weight (g) [a]	Mean	1.8443	1.7190
	SD	0.3004	0.3862
	N	19	20
	%Diff	-	-6.7948
Lung Weight (g) [a]	Mean	0.2007	0.2132
	SD	0.0294	0.0348
	N	19	20
	%Diff	-	6.2116

[a] - Anova & Dunnett

Table 9

Summary of absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Ovary Weight (g) [a]	Mean	0.0264	0.0236
	SD	0.0060	0.0100
	N	18	20
	%Diff	-	-10.7579
Spleen Weight (g) [a]	Mean	0.1314	0.1243
	SD	0.0240	0.0266
	N	19	20
	%Diff	-	-5.3806
Thymus Weight (g) [a]	Mean	0.0406	0.0317 *
	SD	0.0140	0.0108
	N	19	20
	%Diff	-	-21.9819
Uterus/Cervix/Oviduct (g) [a]	Mean	0.2682	0.2487
	SD	0.1266	0.0993
	N	19	20
	%Diff	-	-7.2930

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 10

Summary of organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Brain (%) [a]	Mean	1.36854	1.30788*
	SD	0.09513	0.08612
	N	20	20
	%Diff	-	-4.43258
Epididymis (%) [a]	Mean	0.30512	0.30401
	SD	0.03705	0.03933
	N	20	20
	%Diff	-	-0.36389
Gland, Adrenal (%) [a]	Mean	0.01840	0.01691
	SD	0.00585	0.00427
	N	20	20
	%Diff	-	-8.09912
Gland, Pituitary (%) [a]	Mean	0.00660	0.00689
	SD	0.00191	0.00166
	N	20	20
	%Diff	-	4.31479
Gland, Prostate (%) [a]	Mean	0.07467	0.08623
	SD	0.04793	0.05287
	N	20	20
	%Diff	-	15.47502
Heart (%) [a]	Mean	0.62386	0.56850*
	SD	0.07514	0.05419
	N	20	20
	%Diff	-	-8.87482
Kidney (%) [a]	Mean	1.88210	1.85092
	SD	0.20819	0.13051
	N	20	20
	%Diff	-	-1.65649
Liver/Gallbladder (%) [a]	Mean	5.93804	6.20645*
	SD	0.25137	0.48247
	N	20	20
	%Diff	-	4.52019

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 10

Summary of organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Lung (%) [a]	Mean	0.68006	0.59935*
	SD	0.14913	0.05533
	N	20	20
	%Diff	-	-11.86839
Spleen (%) [a]	Mean	0.24370	0.31106***
	SD	0.03279	0.04568
	N	20	20
	%Diff	-	27.64470
Testis (%) [a]	Mean	0.71473	0.70299
	SD	0.10027	0.10462
	N	20	20
	%Diff	-	-1.64311
Thymus (%) [a]	Mean	0.08202	0.08676
	SD	0.01879	0.01899
	N	20	20
	%Diff	-	5.78071

[a] - Anova & Dunnett: * = $p \leq 0.05$; *** = $p \leq 0.001$

Table 10

Summary of organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Brain (%) [a]	Mean	1.69173	1.65788
	SD	0.14591	0.13403
	N	20	20
	%Diff	-	-2.00084
Gland, Adrenal (%) [a]	Mean	0.03343	0.03609
	SD	0.00833	0.00819
	N	20	20
	%Diff	-	7.96044
Gland, Pituitary (%) [a]	Mean	0.01030	0.00905 *
	SD	0.00190	0.00132
	N	20	20
	%Diff	-	-12.09317
Heart (%) [a]	Mean	0.57946	0.58598
	SD	0.04233	0.04589
	N	20	20
	%Diff	-	1.12561
Kidney (%) [a]	Mean	1.38134	1.42328
	SD	0.08246	0.12737
	N	20	20
	%Diff	-	3.03575
Liver/Gallbladder (%) [a]	Mean	5.91180	6.12969
	SD	0.48393	0.78222
	N	20	20
	%Diff	-	3.68576
Lung (%) [a]	Mean	0.69198	0.70668
	SD	0.04809	0.05814
	N	20	20
	%Diff	-	2.12504
Ovary (%) [a]	Mean	0.08001	0.08536
	SD	0.03066	0.01467
	N	20	20
	%Diff	-	6.69143

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 10

Summary of organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Spleen (%) [a]	Mean	0.41039	0.56592***
	SD	0.06890	0.12315
	N	20	20
	%Diff	-	37.89718
Thymus (%) [a]	Mean	0.14401	0.13864
	SD	0.03869	0.03773
	N	20	20
	%Diff	-	-3.73430
Uterus/Cervix/Oviduct (%) [a]	Mean	0.85530	0.71813
	SD	0.31389	0.23726
	N	20	20
	%Diff	-	-16.03707

[a] - Anova & Dunnett: *** = $p \leq 0.001$

Table 10

Summary of organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Brain (%) [a]	Mean	1.23810	1.31265*
	SD	0.11624	0.08203
	N	20	20
	%Diff	-	6.02166
Epididymis (%) [a]	Mean	0.29244	0.29712
	SD	0.02692	0.03373
	N	20	20
	%Diff	-	1.60226
Gland, Adrenal (%) [a]	Mean	0.01382	0.01351
	SD	0.00521	0.00547
	N	20	20
	%Diff	-	-2.24380
Gland, Pituitary (%) [a]	Mean	0.00639	0.00673
	SD	0.00124	0.00177
	N	20	20
	%Diff	-	5.27988
Gland, Prostate (%) [a]	Mean	0.06406	0.06601
	SD	0.03186	0.04087
	N	20	20
	%Diff	-	3.04503
Heart (%) [a]	Mean	0.55174	0.60077**
	SD	0.05788	0.04495
	N	20	20
	%Diff	-	8.88711
Kidney (%) [a]	Mean	1.67556	1.89759**
	SD	0.21094	0.25627
	N	20	20
	%Diff	-	13.25162
Liver/Gallbladder (%) [a]	Mean	5.87604	5.84964
	SD	0.43419	0.40901
	N	20	20
	%Diff	-	-0.44932

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

Table 10

Summary of organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Lung (%) [a]	Mean	0.58957	0.62309
	SD	0.11557	0.07325
	N	20	20
	%Diff	-	5.68407
Spleen (%) [a]	Mean	0.24575	0.25152
	SD	0.04593	0.04534
	N	20	20
	%Diff	-	2.34819
Testis (%) [a]	Mean	0.64216	0.69523 *
	SD	0.07054	0.08374
	N	20	20
	%Diff	-	8.26391
Thymus (%) [a]	Mean	0.07305	0.07145
	SD	0.02991	0.02332
	N	20	20
	%Diff	-	-2.18999

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 10

Summary of organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Brain (%) [a]	Mean	1.63912	1.69490
	SD	0.14333	0.17172
	N	19	20
	%Diff	-	3.40310
Gland, Adrenal (%) [a]	Mean	0.03248	0.02976
	SD	0.02181	0.01062
	N	19	20
	%Diff	-	-8.36642
Gland, Pituitary (%) [a]	Mean	0.01081	0.01037
	SD	0.00240	0.00234
	N	19	20
	%Diff	-	-4.05385
Heart (%) [a]	Mean	0.55964	0.56541
	SD	0.09144	0.06239
	N	19	20
	%Diff	-	1.03021
Kidney (%) [a]	Mean	1.30762	1.35915
	SD	0.12551	0.11881
	N	19	20
	%Diff	-	3.94142
Liver/Gallbladder (%) [a]	Mean	5.77827	5.54879
	SD	0.54774	0.70906
	N	19	20
	%Diff	-	-3.97138
Lung (%) [a]	Mean	0.63038	0.69643 *
	SD	0.06570	0.10318
	N	19	20
	%Diff	-	10.47829
Ovary (%) [a]	Mean	0.08370	0.07489
	SD	0.01829	0.02407
	N	18	20
	%Diff	-	-10.52328

[a] - Anova & Dunnett: * = $p \leq 0.05$

Table 10

Summary of organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date		70 ul Group 1	70 ul Group 2
Spleen (%) [a]	Mean	0.41286	0.40322
	SD	0.06623	0.06206
	N	19	20
	%Diff	-	-2.33583
Thymus (%) [a]	Mean	0.13029	0.10399
	SD	0.04861	0.03592
	N	19	20
	%Diff	-	-20.18511
Uterus/Cervix/Oviduct (%) [a]	Mean	0.85823	0.82249
	SD	0.41588	0.36089
	N	19	20
	%Diff	-	-4.16382

[a] - Anova & Dunnett

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
ARTERY, AORTA				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
BONE MARROW SMEAR				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
BONE MARROW, STERNUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
BONE, FEMUR				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
BONE, STERNUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
BRAIN				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
CERVIX				
Submitted	.	.	20	20
No Visible Lesions	.	.	20	20
EPIDIDYMIS				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
ESOPHAGUS				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
EYE				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GALLBLADDER				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GALT				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
GANGLION, DORSAL ROOT				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, ADRENAL				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, HARDERIAN				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, MAMMARY				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, PARATHYROID				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, PITUITARY				
Submitted	20	20	19	20
No Visible Lesions	20	20	20	20
GLAND, PROSTATE				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
GLAND, SALIVARY, MANDIBULAR				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, SALIVARY, PAROTID				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
GLAND, SEMINAL VESICLE				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
GLAND, THYROID				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
HEART				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
HINDLIMB, LEFT				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
HINDLIMB, RIGHT				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
KIDNEY				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
LARGE INTESTINE, CECUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
LARGE INTESTINE, COLON				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
LARGE INTESTINE, RECTUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
LIVER				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	19
Prominent lobular architecture	0	0	0	1
LUNG				
Submitted	20	20	20	20
No Visible Lesions	18	20	20	20
Abnormal consistency	1	0	0	0
Focus, dark	1	0	0	0
Focus, pale	1	0	0	0
LYMPH NODE, INGUINAL				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
LYMPH NODE, LUMBAR				
Submitted	.	.	0	1
Enlargement	.	.	.	1

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
LYMPH NODE, MANDIBULAR				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
LYMPH NODE, MESENTERIC				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
MUSCLE, SKELETAL				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
NERVE, OPTIC				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
NERVE, SCIATIC				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
OVARY				
Submitted	.	.	20	20
No Visible Lesions	.	.	19	20
Cyst, clear	.	.	1	0
OVIDUCT				
Submitted	.	.	20	20
No Visible Lesions	.	.	20	20
PANCREAS				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
SITE, ADMINISTRATION, 1				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
SITE, ADMINISTRATION, 2				
Submitted	20	20	20	20
No Visible Lesions	19	18	20	19
Discoloration, dark	1	2	0	1
SKIN				
Submitted	20	20	20	20
No Visible Lesions	20	20	19	20
Thin hair coat	0	0	1	0

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
SMALL INTESTINE, DUODENUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
SMALL INTESTINE, ILEUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
SMALL INTESTINE, JEJUNUM				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
SPINAL CORD				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
SPLEEN				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
STOMACH				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
TESTIS				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
THYMUS				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
TONGUE				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
TRACHEA				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
URETER				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20
URINARY BLADDER				
Submitted	20	20	20	20
No Visible Lesions	20	20	20	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
UTERUS				
Submitted	.	.	20	20
No Visible Lesions	.	.	20	20
VAGINA				
Submitted	.	.	20	20
No Visible Lesions	.	.	20	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
ARTERY, AORTA				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
BONE MARROW SMEAR				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
BONE MARROW, STERNUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
BONE, FEMUR				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
BONE, STERNUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
BRAIN				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
CERVIX				
Submitted	.	.	19	20
No Visible Lesions	.	.	19	20
EPIDIDYMIS				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
ESOPHAGUS				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
EYE				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GALLBLADDER				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GALT				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
GANGLION, DORSAL ROOT				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, ADRENAL				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, HARDERIAN				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, MAMMARY				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, PARATHYROID				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, PITUITARY				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, PROSTATE				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
GLAND, SALIVARY, MANDIBULAR				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, SALIVARY, PAROTID				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
GLAND, SEMINAL VESICLE				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
GLAND, THYROID				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
HEART				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
HINDLIMB, LEFT				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
HINDLIMB, RIGHT				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
KIDNEY				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
LARGE INTESTINE, CECUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
LARGE INTESTINE, COLON				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
LARGE INTESTINE, RECTUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
LIVER				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	19
Prominent lobular architecture	0	0	0	1
LUNG				
Submitted	20	20	19	20
No Visible Lesions	20	18	18	20
Focus, dark	0	0	1	0
Discoloration, mottled	0	2	0	0
LYMPH NODE, INGUINAL				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
LYMPH NODE, MANDIBULAR				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
LYMPH NODE, MESENTERIC				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
MUSCLE, SKELETAL				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
NERVE, OPTIC				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
NERVE, SCIATIC				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
OVARY				
Submitted	.	.	18	20
No Visible Lesions	.	.	18	18
Not Examined: Lost During Necropsy.	.	.	1	0
Cyst, dark	.	.	0	1
Focus, dark	.	.	0	1
OVIDUCT				
Submitted	.	.	19	20
No Visible Lesions	.	.	19	20
PANCREAS				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SITE, ADMINISTRATION, 1				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SITE, ADMINISTRATION, 2				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SKIN				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SMALL INTESTINE, DUODENUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SMALL INTESTINE, ILEUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
SMALL INTESTINE, JEJUNUM				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SPINAL CORD				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
SPLEEN				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
STOMACH				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
TESTIS				
Submitted	20	20	.	.
No Visible Lesions	20	20	.	.
THYMUS				
Submitted	20	20	19	20
No Visible Lesions	19	20	19	20
Small	1	0	0	0
TONGUE				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
TRACHEA				
Submitted	20	20	19	20
No Visible Lesions	19	20	19	20
Fluid accumulation, pale	1	0	0	0
URETER				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
URINARY BLADDER				
Submitted	20	20	19	20
No Visible Lesions	20	20	19	20
UTERUS				
Submitted	.	.	19	20
No Visible Lesions	.	.	19	20

Table 11

Summary of macroscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
VAGINA				
Submitted	.	.	19	20
No Visible Lesions	.	.	19	20

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
ARTERY, AORTA				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
BONE MARROW, STERNUM				
Examined	10	9	10	10
No Visible Lesions	9	9	10	8
Not Examined: Not Present In Wet Tissues.	0	1	.	.
Hematopoietic cells, increased	1	0	0	2
.... minimal	0	0	0	2
.... mild	1	0	0	0
BONE, FEMUR				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
BONE, STERNUM				
Examined	10	9	10	10
No Visible Lesions	10	9	10	10
Not Examined: Not Present In Section.	0	1	.	.
BRAIN				
Examined	10	10	10	10
No Visible Lesions	9	10	10	10
Accumulation, adipocyte; choroid plexus	1	0	0	0
.... minimal	1	0	0	0
EPIDIDYMIS				
Examined	10	10	.	.
No Visible Lesions	10	10	.	.
ESOPHAGUS				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
EYE				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
GALLBLADDER				
Examined	10	10	10	9
No Visible Lesions	10	10	10	9
Not Examined: Not Present In Section.	.	.	0	1

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
GALT				
Examined	9	10	9	9
No Visible Lesions	9	10	9	9
Not Examined: Not Present In Section.	1	0	0	1
Not Examined: Not Present In Wet Tissues.	.	.	1	0
GLAND, ADRENAL				
Examined	10	10	10	10
No Visible Lesions	9	9	8	6
Hyperplasia; subcapsular cell	1	1	2	4
.... minimal	1	1	2	4
GLAND, HARDERIAN				
Examined	10	10	10	10
No Visible Lesions	7	7	6	8
Dilatation	3	3	4	2
.... minimal	3	3	4	2
GLAND, MAMMARY				
Examined	5	9	10	10
No Visible Lesions	5	9	10	10
Not Examined: Not Present In Section.	5	0	.	.
Not Examined: Not Present In Wet Tissues.	0	1	.	.
GLAND, PARATHYROID				
Examined	7	8	6	7
No Visible Lesions	7	8	6	7
Not Examined: Not Present In Section.	3	2	4	3
GLAND, PITUITARY				
Examined	10	10	9	10
No Visible Lesions	9	10	9	10
Not Examined: Not Present In Wet Tissues.	.	.	1	0
Cyst; pars distalis	1	0	0	0
GLAND, PROSTATE				
Examined	10	10	.	.
No Visible Lesions	9	9	.	.
Infiltration, mononuclear cell; interstitial	1	1	.	.
.... minimal	1	1	.	.

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
GLAND, SALIVARY, MANDIBULAR				
Examined	10	10	10	10
No Visible Lesions	10	10	9	9
Infiltration, mononuclear cell; interstitial	0	0	1	1
.... minimal	0	0	1	1
GLAND, SALIVARY, PAROTID				
Examined	10	10	10	10
No Visible Lesions	7	10	10	10
Infiltration, mononuclear cell; interstitial	2	0	0	0
.... minimal	2	0	0	0
Infiltration, mononuclear cell; perivascular	1	0	0	0
.... minimal	1	0	0	0
GLAND, SEMINAL VESICLE				
Examined	10	10	.	.
No Visible Lesions	10	10	.	.
GLAND, THYROID				
Examined	10	10	10	10
No Visible Lesions	9	8	7	8
Cyst; follicle	0	1	2	1
.... minimal	0	1	2	1
Ectopia; thymic	1	1	1	1
HEART				
Examined	10	10	10	10
No Visible Lesions	8	9	10	10
Infiltration, mononuclear cell; perivascular	2	0	0	0
.... minimal	2	0	0	0
Infiltration, mononuclear cell; ventricular free wall	0	1	0	0
.... minimal	0	1	0	0
KIDNEY				
Examined	10	10	10	10
No Visible Lesions	3	3	5	5
Infiltration, mononuclear cell; interstitial	7	4	0	1
.... minimal	7	4	0	1
Infiltration, mononuclear cell; pelvis	0	2	0	0
.... minimal	0	2	0	0

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
KIDNEY (Continued...)				
Infiltration, mononuclear cell; perivascular, pelvis	0	0	4	2
.... minimal	0	0	4	2
Basophilia; tubular	2	2	3	2
.... minimal	2	2	3	2
Cyst; tubular	1	0	1	0
.... minimal	1	0	1	0
LARGE INTESTINE, CECUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
LARGE INTESTINE, COLON				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
LARGE INTESTINE, RECTUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
LIVER				
Examined	10	10	10	10
No Visible Lesions	9	9	9	10
Hypertrophy; centrilobular	1	0	0	0
.... minimal	1	0	0	0
Infiltration, mononuclear cell; perivascular	0	1	0	0
.... minimal	0	1	0	0
Inflammation, mononuclear cell	0	0	1	0
.... minimal	0	0	1	0
LUNG				
Examined	10	10	10	10
No Visible Lesions	8	10	8	9
Congestion; agonal	1	0	0	0
.... mild	1	0	0	0
Aggregate; macrophage	1	0	1	1
.... minimal	1	0	1	1
Metaplasia; osseous	0	0	1	0
.... minimal	0	0	1	0

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
LYMPH NODE, INGUINAL				
Examined	9	9	10	10
No Visible Lesions	9	9	10	9
Not Examined: Not Present In Wet Tissues.	1	1	.	.
Cellularity, increased; lymphoid	0	0	0	1
.... minimal	0	0	0	1
LYMPH NODE, LUMBAR				
Examined	.	.	0	1
No Visible Lesions	.	.	.	1
LYMPH NODE, MANDIBULAR				
Examined	10	10	9	9
No Visible Lesions	10	10	9	9
Not Examined: Not Present In Wet Tissues.	.	.	1	1
LYMPH NODE, MESENTERIC				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
MUSCLE, SKELETAL				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
NERVE, OPTIC				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
NERVE, SCIATIC				
Examined	10	10	10	10
No Visible Lesions	10	1	8	1
Infiltration, mixed cell; perineurial	0	4	2	8
.... minimal	0	4	2	8
Infiltration, mononuclear cell; perineurial	0	5	0	1
.... minimal	0	5	0	1
OVARY				
Examined	.	.	10	10
No Visible Lesions	.	.	10	10
OVIDUCT				
Examined	.	.	10	10
No Visible Lesions	.	.	10	10

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
PANCREAS				
Examined	10	10	10	10
No Visible Lesions	8	10	9	10
Infiltration, mononuclear cell; adipose tissue	1	0	1	0
.... minimal	1	0	1	0
Infiltration, mononuclear cell; perivascular, adipose tissue	1	0	0	0
.... minimal	1	0	0	0
SITE, ADMINISTRATION, 1				
Examined	10	10	10	10
No Visible Lesions	2	0	3	0
Edema; subcutaneous tissue	8	9	7	5
.... minimal	8	9	7	5
Hemorrhage; subcutaneous tissue	0	0	0	1
.... minimal	0	0	0	1
Inflammation, mononuclear cell; subcutaneous tissue; myofiber	2	6	0	3
.... minimal	2	6	0	3
Inflammation, mixed cell; subcutaneous tissue; myofiber	0	4	1	7
.... minimal	0	4	1	7
SITE, ADMINISTRATION, 2				
Examined	10	10	10	10
No Visible Lesions	0	0	0	1
Edema; subcutaneous tissue	9	9	10	4
.... minimal	9	9	10	4
Hemorrhage; subcutaneous tissue	2	2	0	2
.... minimal	2	2	0	2
Congestion; subcutaneous tissue	1	0	0	0
.... minimal	1	0	0	0
Inflammation, mixed cell; subcutaneous tissue; myofiber	0	4	1	8
.... minimal	0	4	1	8
Inflammation, mononuclear cell; subcutaneous tissue; myofiber	4	6	0	1
.... minimal	4	6	0	1
SKIN				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
SMALL INTESTINE, DUODENUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SMALL INTESTINE, ILEUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SMALL INTESTINE, JEJUNUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SPINAL CORD				
Examined	10	10	10	10
No Visible Lesions	5	5	3	6
Vacuolation; neuronal, ganglion; dorsal root	5	5	7	3
.... minimal	5	5	7	3
Cyst; squamous	0	0	0	1
.... minimal	0	0	0	1
SPLEEN				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
STOMACH				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
TESTIS				
Examined	10	10	.	.
No Visible Lesions	10	10	.	.
THYMUS				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
TONGUE				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
TRACHEA				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): TERMINAL EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
URETER				
Examined	9	10	9	10
No Visible Lesions	9	10	9	10
Not Examined: Not Present In Section.	1	0	1	0
URINARY BLADDER				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
VAGINA				
Examined	.	.	10	10
No Visible Lesions	.	.	10	10
UTERUS/CERVIX				
Examined	.	.	10	10
No Visible Lesions	.	.	10	10
NO CORRELATE				
Examined	.	.	0	1
No correlating lesion	.	.	.	1

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
ARTERY, AORTA				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
BONE MARROW, STERNUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
BONE, FEMUR				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
BONE, STERNUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
BRAIN				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
EPIDIDYMIS				
Examined	10	10	.	.
No Visible Lesions	10	10	.	.
ESOPHAGUS				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
EYE				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
GALLBLADDER				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
GALT				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
GLAND, ADRENAL				
Examined	10	10	10	10
No Visible Lesions	9	8	9	9
Hyperplasia; subcapsular cell	1	2	1	1
.... minimal	1	2	1	1

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
GLAND, HARDERIAN				
Examined	10	10	10	10
No Visible Lesions	8	10	5	9
Dilatation	2	0	5	1
.... minimal	2	0	5	1
Infiltration, mononuclear cell	0	0	2	0
.... minimal	0	0	2	0
GLAND, MAMMARY				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
GLAND, PARATHYROID				
Examined	7	8	7	10
No Visible Lesions	7	8	7	10
Not Examined: Not Present In Section.	3	2	3	0
GLAND, PITUITARY				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
GLAND, PROSTATE				
Examined	10	10	.	.
No Visible Lesions	10	10	.	.
GLAND, SALIVARY, MANDIBULAR				
Examined	10	10	10	10
No Visible Lesions	9	10	8	10
Infiltration, mononuclear cell	1	0	2	0
.... minimal	1	0	2	0
GLAND, SALIVARY, PAROTID				
Examined	10	10	9	10
No Visible Lesions	10	10	9	10
Not Examined: Not Present In Section.	.	.	1	0
GLAND, SEMINAL VESICLE				
Examined	10	10	.	.
No Visible Lesions	10	10	.	.
GLAND, THYROID				
Examined	10	10	10	10
No Visible Lesions	7	7	7	5

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
GLAND, THYROID (Continued...)				
Cyst	3	3	1	2
.... minimal	3	3	1	2
Ectopia; thymic	0	0	3	4
HEART				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
KIDNEY				
Examined	10	10	10	10
No Visible Lesions	2	4	7	8
Infiltration, mononuclear cell; interstitial	5	5	2	1
.... minimal	5	5	2	1
Basophilia; tubular	5	2	1	2
.... minimal	5	2	1	2
Cyst; tubular	1	1	0	0
.... minimal	1	1	0	0
LARGE INTESTINE, CECUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
LARGE INTESTINE, COLON				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
LARGE INTESTINE, RECTUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
LIVER				
Examined	10	10	10	10
No Visible Lesions	9	10	7	9
Necrosis	0	0	1	0
.... minimal	0	0	1	0
Infiltration, mononuclear cell	1	0	3	1
.... minimal	1	0	3	1
LUNG				
Examined	10	10	10	10
No Visible Lesions	10	8	9	10

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
LUNG (Continued...)				
Congestion; agonal	0	2	1	0
.... minimal	0	2	1	0
Aggregate; macrophage	0	0	1	0
.... minimal	0	0	1	0
LYMPH NODE, INGUINAL				
Examined	8	10	10	9
No Visible Lesions	8	10	10	9
Not Examined: Not Present In Section.	2	0	0	1
LYMPH NODE, MANDIBULAR				
Examined	9	9	10	10
No Visible Lesions	9	9	10	10
Not Examined: Not Present In Section.	1	1	.	.
LYMPH NODE, MESENTERIC				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
MUSCLE, SKELETAL				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
NERVE, OPTIC				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
NERVE, SCIATIC				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
OVARY				
Examined	.	.	9	10
No Visible Lesions	.	.	9	9
Not Examined: Lost During Necropsy.	.	.	1	0
Cyst; epithelial	.	.	0	1
.... minimal	.	.	0	1
Congestion	.	.	0	1
.... minimal	.	.	0	1
OVIDUCT				
Examined	.	.	10	10

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
OVIDUCT (Continued...)				
No Visible Lesions	.	.	10	10
PANCREAS				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SITE, ADMINISTRATION, 1				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SITE, ADMINISTRATION, 2				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SKIN				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SMALL INTESTINE, DUODENUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SMALL INTESTINE, ILEUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SMALL INTESTINE, JEJUNUM				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
SPINAL CORD				
Examined	10	10	10	10
No Visible Lesions	5	8	5	3
Vacuolation; neuronal, dorsal root; ganglion	5	2	5	7
.... minimal	5	2	5	7
SPLEEN				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
STOMACH				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
TESTIS				
Examined	10	10	.	.

Table 12

Summary of microscopic pathology

513351

Removal Reason(s): RECOVERY EUTHANASIA Summary: Incidence	Male		Female	
	70 ul Group 1	70 ul Group 2	70 ul Group 1	70 ul Group 2
TESTIS (Continued...)				
No Visible Lesions	9	9	.	.
Hypospermatogenesis	1	1	.	.
.... minimal	1	1	.	.
THYMUS				
Examined	10	10	10	10
No Visible Lesions	9	10	10	10
Atrophy	1	0	0	0
.... mild	1	0	0	0
TONGUE				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
TRACHEA				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
URETER				
Examined	10	10	9	9
No Visible Lesions	10	10	9	9
Not Examined: Not Present In Section.	.	.	1	1
URINARY BLADDER				
Examined	10	10	10	10
No Visible Lesions	10	10	10	10
VAGINA				
Examined	.	.	10	10
No Visible Lesions	.	.	10	10
UTERUS/CERVIX				
Examined	.	.	10	10
No Visible Lesions	.	.	10	10
NO CORRELATE				
Examined	.	.	0	2
No correlating lesion	.	.	.	2

Appendix 1
Last amended protocol and protocol

PROTOCOL AMENDMENT 13

Test Facility Study No. 513351

Sponsor Reference No. 1156PM

AstraZeneca Project Name: AZD1222

AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

SPONSOR:
AstraZeneca R&D Cambridge
da Vinci Building
Melbourn Science Park
Cambridge Road
Melbourn
Hertfordshire SG8 6HB
UK

TEST FACILITY
Charles River Laboratories Edinburgh Ltd
Elphinstone Research Centre
Tranent, East Lothian
EH33 2NE
UK

Appendix 1

SUMMARY OF CHANGES AND JUSTIFICATIONS

Protocol effective date: 25 Aug 2020

Note: When applicable, additions are indicated in underlined text and deletions are indicated in strikethrough text directly in the affected sections of the document.

Item or Section(s)	Justification
Amendment 1	**Date: 03 Sep 2020**
5.2. Sponsor	To clarify that inspections of the immunogenicity phase will be study based.
9.1. Test Item(s)	To include test item details on receipt of the test item and associated paperwork.
9.2. Control Item Components	To include control item details on receipt of the control item and associated paperwork.
14. Experimental Design 14.3. Justification of Route and Dosage Levels	To update viral particle concentration to match test item documentation.
16.2.1. Immunogenicity Sample Collection	Clarification that serum separator tubes will be used for the immunogenicity bleeds to improve a serum yield.
Amendment 2	**Date: 07 Sep 2020**
4. Regulatory Compliance	The stability of the test item has not currently been conducted in accordance with the principles of GLP and therefore an exception to the GLP has been documented for the time being. The intention is to retrospectively perform the stability and concentration assessment of the test item at a later date, after which the exception to GLP will be removed (assuming the appropriate stability is determined).
9.2. Control Item Components	Clarification that the control item will be stored in a refrigerator set to maintain 2-8°C, not 4°C.
9.4. Analysis of Test Item	Information added to clarify that the stability of the test item was not conducted in accordance with the principles of GLP and therefore, will be dispensed on the morning of dosing. The intention is to retrospectively perform the stability and concentration assessment of the test item at a later date, after which the exception to GLP will be removed (assuming the appropriate stability is determined).
14.1. Administration of Test and Control Items	Clarification that the doses will be administered to the thigh of the hindlimb.
Amendment 3	**Date: 09 Sep 2020**
15.3. Body Temperature	Based on review of the Day 1, 4 hour post dose body temperature a body temperature will be collected at 24 hours post the first dose and on Day 22, pre-dose, 4 and 24 hours post dose.
Amendment 4	**Date: 02 Oct 2020**
8. Responsible Personnel	To document the change in Clinical Pathology Reviewer.
11.1. Preparation of Control Item	In error, the protocol stated that the control item would be removed from the freezer, however, this should have stated refrigerator. Additionally, the control item name had been added to the preparation section.
Amendment 5	**Date: 15 Oct 2020**
2. Proposed Study Schedule	In discussion with the Sponsor, reporting timelines amended.
8. Responsible Personnel	In discussion with the Sponsor, the immunogenicity data will be interpreted by a scientist at the Test Facility. Section updated accordingly.

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Item or Section(s)	Justification
17.5. Tissue Collection and Preservation	Instruction for the gallbladder to be collected and evaluated microscopically added as this was missing in error.
Amendment 6	**Date: 21 Oct 2020**
17.5. Tissue Collection and Preservation	Clarification that the gallbladder will be collected and weighed with the liver. Clarification that the right and left hindlimbs will be collected at necropsy. In discussion with the Sponsor, the dorsal root ganglion will be collected at necropsy and therefore, has been added to the tissue collection list.
23. Reporting	To update standard wording as the report will now be electronically signed.
Amendment 7	**Date: 27 Oct 2020**
17.5. Tissue Collection and Preservation	Clarification that the sections of the spinal cord will be processed in situ.
20.2. Statistical Analysis	Clarification that haematology and clinical chemistry data will be statistically analysed.
Amendment 8	**Date: 04 Nov 2020**
18.2. Histopathology 18.3. Pathology Peer Review 19. Computerised Systems 22. Retention of Records, Samples and Specimens	To document the usage of Whole Slide Imaging (WSI) in histopathological evaluation.
24.1. Home Office Project Licence No.	The project licence for the toxicity of Pharmaceuticals was recently renewed at the Test Facility and therefore, the study protocol has been updated to reflect the new project licence and project licence protocol number. The updated project licence is effective from 04 Nov 2020.
Amendment 9	**Date: 23 Nov 2020**
6. Communication	To update the communication email at request of the Sponsor.
16.2.3. Immunogenicity Sample Analysis	Analytical information added for the immunogenicity samples and clarification that the data will be interpreted by a scientist at the test facility.
Attachments	To add the immunogenicity bioanalysis phase plan as an attachment.
Amendment 10	**Date: 24 Nov 2020**
16.2.3. Immunogenicity Sample Analysis	To update wording at the request of the sponsor to clarify how the data will be presented.
Attachments	The phase plan in attachment 1 has been included as a PDF attachment rather than a word document attachment (as in the previous amendment) for formatting purposes.
Amendment 11	**Date: 04 Dec 2020**
4. Regulatory Compliance	The stability of the test item (which was used as supplied) has now been generated in compliance with the principles of GLP. Therefore, the exception to GLP ha been removed from the protocol. The stability data, which was generated in compliance with the principles of GLP, was provided to the study director and is retained in the study data.
8. Responsible Personnel	To document the PI's reference number for the immunogenicity phase of the study.
9.4. Analysis of Test Item	The stability of the test item (which was used as supplied) has now been generated in compliance with the principles of GLP. Therefore, the exception to GLP ha been removed from the protocol. The stability data,

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Item or Section(s)	Justification
	which was generated in compliance with the principles of GLP, was provided to the study director and is retained in the study data.
19. Computerised Systems	To document the computerised systems for the immunogenicity phase of the study.
Amendment 12	**Date: 08 Dec 2020**
4. Regulatory Compliance 9.4. Analysis of Test Item	In error, the previous amendment removed the non-compliance for the stability of the test item. This occurred as when reviewing the updated stability memo, the Study Director incorrectly read that this was done to GLP, however, the stability data was generated in accordance with GMP. Section 9.4 has been updated to include information that the stability was performed in accordance with GMP.
Amendment 13	
15.7. Irwin Screen Observations	Clarification that the Irwin screen performed was not modified and this was titled incorrectly in the original protocol. As the protocol and final amendment is presented in the final report, this is being updated for clarity.

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1. OBJECTIVE(S)

AZD1222 is a recombinant, replicant defective adenovirus (ChAdOx1 nCov-19) expressing the SARS-CoV-2 spike (S) surface glycoprotein which is under development by AstraZeneca as a potential COVID-19 disease prevention vaccine. The objective of this study is to determine the potential toxicity of AZD1222 when given by intramuscular injection intermittently (on Days 1, 22 and 43) to mice with a minimum 28 day recovery period to evaluate the potential reversibility of any findings. In addition the antibody response will be evaluated.

1.1. Study Classification

Study Category:	Toxicology
Study Type:	Repeat Dose Toxicity
Study Design:	Parallel
Primary Treatment CAS Registry Number:	Not Available
Primary Treatment Unique Ingredient ID:	Not Available
Class of Compound:	Not Available

2. PROPOSED STUDY SCHEDULE

Proposed study dates are listed below. Actual applicable dates will be included in the Final Report.

Experimental Start Date:	01 Sep 2020 (First date of study-specific data collection)
Experimental Completion Date:	Jan 2021 (Last date data are collected from the study)
Animal Arrival/Transfer:	25 Aug 2020
Initiation of Dosing:	08 Sep 2020
Completion of In-life:	
Main Study:	22 Oct 2020
Recovery:	20 Nov 2020 (Dates of necropsy)
Immunogenicity Sample Despatch:	Delivery 1: 30 Sep 2020 Delivery 2: 21 Oct 2020 Delivery 3: 23 Nov 2020
Clinical Pathology Review (Main Study):	05 Nov 2020 (10 business days from first necropsy)
Clinical Pathology Review (Recovery):	04 Dec 2020 (10 business days from last necropsy)

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Audited Draft Immunogenicity Report:	08 Dec 2020 (11 business days from necropsy)
Irwin Measurements Draft Report:	10 Dec 2020 (45 business days from the Day 29 Irwin measurement)
Main Study Pathology Draft Report and Slides Available for Sponsor Peer Review:	27 Nov 2020 (26 business days from first necropsy)
Scanning of Main Study Pathology Slides for Peer Review:	27 Nov 2020 (26 business days from first necropsy)
Pathology Draft Report (Main Study only) After Sponsor Peer Review:	04 Dec 2020 (31 business days from first necropsy)
Full Pathology Draft Report (including recovery) and Slides Available for Sponsor Peer Review:	24 Dec 2020 (24 business days from last necropsy)
Scanning of Recovery Pathology Slides for Peer Review:	24 Dec 2020 (24 business days from last necropsy)
Pathology Draft Report after Sponsor Peer Review:	31 Dec 2020 (27 business days from last necropsy)
Unaudited Draft Report (Excluding Recovery Pathology/Immunogenicity):	08 Dec 2020 (11 business days from last necropsy)
Receipt of Sponsor Comments (Unaudited Draft):	09 Dec 2020 (12 business days from last necropsy)
Audited Draft Report (Excluding Recovery Pathology):	11 Dec 2020 (15 business days from last necropsy)
Receipt of Sponsor Comments (Audited Draft):	24 Dec 2020
Audited Draft Report (Including Recovery Pathology):	08 Jan 2021 (31 business days from last necropsy)
Finalization of Immunogenicity and Irwin Phase Reports:	23 Dec 2020 (23 business days from last necropsy)
Finalization of Pathology Phase Reports and final set of Sponsor Comments:	13 Jan 2021 (34 business days from last necropsy)

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Final Report:	22 Jan 2021 (40 business days from last necropsy) (Expected date of Study Director signature)

* Main study pathology may not be audited at this stage, Study Director will confirm with Sponsor on issue of report.

3. GUIDELINES FOR STUDY DESIGN

The design of this study was based on the study objective(s), the overall product development strategy for the test item, and the following study design guidelines:

- ICH Harmonised Tripartite Guideline S7A. *Guideline on Safety Pharmacology Studies for Human Pharmaceuticals*.
- Committee for Medicinal Products for Human Use (CHMP). *Note for Guidance on Repeated Dose Toxicity*. CPMP/SWP/1042/99rev1.
- ICH Harmonised Tripartite Guideline M3 (R2). *Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals.*
- WHO Guideline on Nonclinical Evaluation of Vaccines, Nov 2005, and WHO Guideline on the Nonclinical Evaluation of Vaccine Adjuvants and Adjuvanted vaccines Oct 2013.
- FDA: Guideline for Industry: Considerations for Development Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications 2006, and Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry; Center for Biologics Evaluation and Research; June 2020.
- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Number 13. *Consensus Document of the Working Group on Good Laboratory Practice. The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies*.

4. REGULATORY COMPLIANCE

This study will be performed in accordance with the OECD Principles of Good Laboratory Practice as incorporated into the United Kingdom Statutory Instrument for GLP and as accepted by Regulatory Authorities throughout the European Union, United States of America (FDA and EPA) and Japan (MHLW, MAFF and METI), and other countries that are signatories to the OECD Mutual Acceptance of Data Agreement.

Exceptions to GLP include the following:

- Pathology Peer Review
- Stability testing of the test item

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5. QUALITY ASSURANCE

5.1. Test Facility

The Test Facility Quality Assurance Unit (QAU) will monitor the study to assure the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with Good Laboratory Practice regulations. The QAU will review the protocol, conduct inspections at intervals adequate to assure the integrity of the study, and audit the Final Report to assure that it accurately describes the methods and standard operating procedures and that the reported results accurately reflect the raw data of the study.

The Test Facility QAU contact for this study is indicated below:

s 22

5.2. Sponsor

The conduct of the following study phase(s) will be audited by the Sponsor QAU(s):

- Immunogenicity

Inspections will be study based and performed per Test Site SOP. For all study phases inspected by Sponsor or Sponsor subcontractor QAU(s), copies of each periodic inspection report will be made available to the Study Director, Test Facility Management and Test Facility QAU.

6. COMMUNICATION

The Study Director will send an electronic version of the study plan (Final Protocol) and any amendments (signed by the Study Director and, when applicable, Test Facility Management) to the Sponsor Representative (Study Monitor), Alternative Sponsor Contact, Clinical Pathology Reviewer (if applicable), s 22 s 22 , s 22 and to each Monitoring Scientist.

7. SPONSOR

Sponsor Representative (Study Monitor)

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Alternative Sponsor Contact

8. RESPONSIBLE PERSONNEL

Study Director

Management Contact

Clinical Pathology Review

Contributing Scientist at the Test Facility

Immunogenicity Interpretation

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Individual Scientists (IS) at Test Facility

Pathology

Irwin Measurements

Each IS is required to report any deviations or other circumstances that could affect the quality or integrity of the study to the Study Director in a timely manner. Each IS will provide a report addressing their assigned phase of the study, which will be included as an appendix to the Final Report. The phase report will include the following:

- A listing of critical computerised systems used in the conduct and/or interpretation of the assigned study phase

Principal Investigators (PI) at Test Site

Immunogenicity

The PI's reference number for this phase of the study is 2020-AZD1222-0217.

Each PI is required to report any deviations or other circumstances that could affect the quality or integrity of the study to the Study Director in a timely manner. Each PI will provide a report addressing their assigned phase of the study, which will be included as an appendix to the Final Report. A draft of the phase report will be submitted to the Study Director for review prior to finalisation. The phase report will include the following:

- A Statement of Compliance
- A QA Statement
- The archive site for all records, samples, specimens and reports generated from the phase or segment (alternatively, details regarding the retention of the materials may be provided to the Study Director for inclusion in the Final Report)

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- A listing of critical computerised systems used in the conduct and/or interpretation of the assigned study phase

Monitoring Scientist (MS) at AstraZeneca

Pathology

Irwin Observations

Clinical Pathology

9. TEST AND CONTROL ITEMS

9.1. Test Item(s)

Identification: AZD1222

Alternative Identification: ChAdOx1-nCovd-19

Supplier: AstraZeneca

Batch (Lot) Number: MS00684-92

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Date of Manufacture: 07 Aug 2020

Expiration Date: 07 Aug 2021

Viral Particle Concentration: 5.3 x10^11/mL

Storage Conditions: In a freezer at approximately -80°C.

Administration Dose Form: Solution

9.2. Control Item Components

Identification: AZD1222 Vehicle

Composition: 10 mM histidine, 7.5% (v/w) sucrose, 35 mM sodium chloride, 1 mM magnesium chloride, 0.1% (v/w) Polysorbate-80, 0.1 mM EDTA and 0.5% (v/w) ethanol, pH 6.6

Supplier: AstraZeneca

Batch (Lot) Number: BN20-1689

Date of Manufacture: 24 Aug 2020

Expiration Date: 24 Feb 2021

Storage Conditions: In a refrigerator set to maintain 2-8°C.

9.3. Test and Control Item Characterisation

The Sponsor will provide to the Test Facility documentation of the identity, strength, purity, composition and stability for the test item. A Test Item (Compound) Characterisation Summary (TICS) and Test formulation Summary (TFS) or equivalent documentation will be provided for retention in the raw data.

The Sponsor has appropriate documentation on file concerning the method of synthesis, fabrication or derivation of the test and control item(s), and this information is available to the appropriate regulatory agencies should it be requested.

9.4. Analysis of Test Item

The stability of the bulk test item will not be determined during the course of this study. Information to support the stability of each lot of the bulk test item will be provided by the Sponsor.

The stability and viral particle concentration of the test item has not currently been conducted in accordance with the principles of GLP, however, this has been conducted in accordance with a high standard of scientific principles. The test item will be used as supplied, and will be removed from frozen storage on the morning of each dosing occasion, and used when thawed and brought to room temperature within the time period stated in the supplied data. The stability and viral particle concentration data generated have been reviewed and are considered to be of a suitable

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quality (performed according to GMP) and therefore, this exception from GLP is considered to have no impact on the outcome or the integrity of the study.

9.5. Reserve Samples

A reserve sample will not be retained at the Test Facility as the Sponsor has indicated that they will retain a reserve sample.

9.6. Test and Control Item Inventory and Disposition

Records of the receipt, distribution, and storage of test and control items will be maintained. The quantity of test item/control item remaining will be communicated to the Study Monitor, who will decide if it should be discarded or returned to the Sponsor.

Shipping Contact

10. SAFETY

Safety instructions for this study are provided on the Sponsor supplied safety data sheet. COSHH assessment and classification will be carried out at the Test Facility on a Chemical Classification Spreadsheet.

11. DOSE FORMULATION AND ANALYSIS

11.1. Preparation of Control Item

The control item, AZD1222 Vehicle, will be dispensed as required. The control item will be removed from the refrigerator on the morning of dosing and delivered to the animal unit on 'wet' ice. On arrival at the animal unit, dosing vials will be allowed to reach room temperature before dosing.

Thawed vials cannot be re-frozen or re-used and will be disposed of after being used for dosing formulation preparation.

Any residual volumes will be discarded unless otherwise requested by the Study Director.

11.2. Preparation of Test Item

The test item, AZD1222, will be administered as received. The required number of vials will be removed from the freezer on the morning of dosing and delivered to the animal unit on 'wet' ice. On arrival at the animal unit, dosing vials will be allowed to reach room temperature before dosing.

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Thawed vials cannot be re-frozen or re-used and will be disposed of after use.

Any residual volumes will be discarded unless otherwise requested by the Study Director.

11.3. Sample Collection and Analysis

The test and control items will be used as received from the Sponsor; therefore, samples for dose formulation analysis will not be collected by the Test Facility.

12. TEST SYSTEM

Species:	Mouse
Strain:	CD-1 Crl:CD-1 (ICR)
Condition:	Purpose-bred, naive
Source:	Charles River UK Limited, Margate, Kent, UK
Number of Males Ordered:	88 (including 3 extras)
Number of Females Ordered:	88 (including 3 extras)
Target Age at the Initiation of Dosing:	7-8 weeks
Target Weight at the Initiation of Dosing:	20-40 g

The actual age and weight of animals will be listed in the Final Report.

12.1. Justification of Test System and Number of Animals

The mouse was chosen as the animal model for this study as it is a rodent species accepted by regulatory agencies for toxicity testing.

The total number of animals to be used in this study is considered to be the minimum required to properly characterise the effects of the test item. This study has been designed such that it does not require an unnecessary number of animals to accomplish its objectives.

12.2. Animal Identification

At study assignment, each animal will be identified using a subcutaneously implanted electronic cylindrical, ‘glass-sealed’ TROVAN microchip.

12.3. Environmental Acclimation

The animals will be allowed to acclimate to the Test Facility rodent toxicology accommodation for a period of up to 3 weeks (minimum of one week) before the commencement of dosing.

12.4. Selection, Assignment, Replacement and Disposition of Animals

Males and females will be randomised separately.

Appendix 1

Cages will be racked by dose group and arranged vertically throughout the rack. Control animals will be housed on a separate rack.

Before the initiation of dosing, any assigned animals considered unsuitable for use in the study will be replaced by alternative animals obtained from the same shipment and maintained under the same environmental conditions.

After initiation of dosing, study animals may be replaced during the replacement period with alternative animals in the event of accidental injury, non-test item-related health issues, or similar circumstances.

The alternative animals may be used as replacements on the study within 3 days.

The disposition of all animals will be documented in the study records.

13. HUSBANDRY

13.1. Housing

Males will be housed individually and females will be housed 2 or 3 per cage (unless reduced by mortality) in solid bottom polyethermide plastic cages with wire bar lid.

Bedding material will be sterilised white wood shavings which will be provided with a certificate of analysis for significant contaminants. An analytical certificate for each batch of bedding used will be retained at the Test Facility.

There are no known contaminants in the bedding that would interfere with the objectives of the study.

13.2. Environmental Conditions

The targeted conditions for animal room environment will be as follows:

Temperature:	19 - 23°C
Humidity:	40 - 70%
Ventilation:	A minimum of 10 air changes per hour
Light Cycle:	12 hours light and 12 hours dark (except when interrupted by study procedures/activities)

There will be automatic control of temperature and humidity which will be continuously monitored and recorded. Information on actual temperature and humidity ranges versus target ranges will be presented in the study report.

The light cycle will be controlled automatically.

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13.3. Food

SDS Rat and Mouse No. 1 Diet SQC Expanded will be provided *ad libitum* throughout the study, except during designated procedures. The same diet in meal form may be provided to individual animals as warranted by clinical signs (e.g. broken/damaged incisors or other health changes).

The feed is analysed by the supplier for nutritional components and environmental contaminants. Results of the analysis are provided by the supplier and will be retained at the Test Facility.

There are no known contaminants in the feed that are considered to interfere with the objectives of the study.

13.4. Water

The animals will have access to water *ad libitum* from the public supply from water bottles which will be changed as necessary throughout the course of the study.

The water used by the Test Facility is analysed at regular intervals for dissolved materials, heavy metals, pesticide residues, pH, nitrates and nitrites. Microbiological screening is also conducted. An analytical certificate for each analysis will be retained at the Test Facility.

The water used is considered not to contain any additional substances, in sufficient concentration, to have any influence on the outcome of the study.

13.5. Animal Enrichment

For psychological/environmental enrichment, males will be provided with items such as a device for hiding in and an object for chewing, except when interrupted by study procedures/activities.

Females will be socially housed for psychological/environmental enrichment and will be provided with items such as a device for hiding in and an object for chewing, except when interrupted by study procedures/activities.

Objects for chewing and devices for hiding in will be provided with a certificate of analysis for significant contaminants. An analytical certificate for each batch of chewing objects and devices for hiding used will be retained at the Test Facility.

Other items may be included to enrich the cage environment. Details will be given in the study report.

13.6. Veterinary Care

Veterinary care will be available throughout the course of the study and animals will be examined by the veterinary staff as warranted by clinical signs or other changes. All veterinary examinations and recommended therapeutic treatments, if any, will be documented in the study records.

In the event that animals show signs of illness or distress, the responsible veterinarian may make initial recommendations about treatment of the animal(s) and/or alteration of study procedures,

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which must be approved by the Study Director or by Test Facility management if the Study Director is not available, except where detailed below where immediate action is required to address a potentially life-threatening situation, or to alleviate acute severe pain. All such actions will be documented in the study records and, when appropriate, by protocol amendment. Treatment of the animal(s) for minor injuries or ailments may be approved without prior consultation with the Sponsor representative when such treatment does not impact fulfilment of the study objectives. If the condition of the animal(s) warrants significant therapeutic intervention or alterations in study procedures, the Sponsor representative will be contacted, when possible, to discuss appropriate action. If the condition of the animal(s) is such that emergency measures must be taken, the Study Director and/or attending veterinarian will attempt to consult with the Sponsor representative prior to responding to the medical crisis, but the Study Director and/or veterinarian has authority to act immediately at his/her discretion to alleviate suffering. The Sponsor representative will be fully informed of any such events.

14. EXPERIMENTAL DESIGN

Experimental Design

Group No.	Animal Numbers					
	Main Study		Recovery		Immunogenicity	
	Males	Females	Males	Females	Males	Females
1	1001-1020	1501-1520	1101-1120	1601-1620	-	-
2	2001-2020	2501-2520	2101-2120	2601-2620	2201-2205	2701-2705

Extra animals will be numbered 3001-3003M and 3501-3503F
- = Not applicable

Group No.	Dose Volume[a] (µL)	Total Viral Particle (VP)/dose	Viral Particle (VP) Concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL will be administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

14.1. Administration of Test and Control Items

The test or control items will be administered to the appropriate animals by intramuscular injection (dose split across two dose sites) on Days 1, 22 and 43. The first day of dosing will be designated as Day 1. The dosing formulations will be allowed to reach room temperature before administration. Animals will generally be dosed during the morning.

The doses will be given using a graduated syringe and sterile hypodermic needle (details of the gauge and type of needle used will be retained in the raw data).

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Each hindlimb (thigh) will receive 0.035 mL, total dose of 0.07 mL.

Left hindlimb = Site 1

Right hindlimb = Site 2

The administration sites will be clipped free of hair before the first injection. The injection site will be marked. Further clipping and marking will occur as necessary to maintain visibility of each site.

14.2. Recovery Period

On completion of the dosing period, the designated recovery animals will be retained for a minimum 28 day recovery period.

14.3. Justification of Route and Dosage Levels

The intramuscular injection route of administration has been selected for this study as this route has been defined by the Sponsor as the route of clinical application.

Regulatory guidelines indicate that the highest proposed clinical dose should be evaluated in the animal model, and an additional dose included (n+1). For this vaccine the clinical dose is not expected to exceed 5x10^10 virus particles/dose with the number of dosing occasions being 2. However, as the dose is limited by the volume that can be administered by intramuscular injection to mice, the maximum feasible dose of 3.7 x10^10 virus particles will be given. On a body weight basis, this exceeds the human exposure by >1000x, assuming 50 kg human and 50 g mouse. Previous data generated for the Sponsor indicated that 1.7x10^10 virus particles/dose in mice induced an appropriate immune response. Charles River Study No. 490838 [1] has shown that 2.6x10^10/dose produced no in-life adverse signs of toxicity.

15. IN-LIFE PROCEDURES, OBSERVATIONS, AND MEASUREMENTS

15.1. Mortality/Moribundity Checks

Frequency:	Twice daily, once at the start and once towards the end of the working day throughout the study.
Procedure:	Animals will be observed for general health/mortality and moribundity. Animals will not be removed from the cage during observation, unless necessary for identification or confirmation of possible findings.

15.2. Clinical Observations

15.2.1. Detailed Clinical Observations

Frequency:	Weekly, beginning Week -1.

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Procedure: Animals removed from the cage for examination.

15.2.2. Pre and Post dose Observations

Frequency: Regularly throughout the day on dosing days. On non-dosing days, signs will be recorded at least once.

Procedure: All the animals will be examined for reaction to AZD1222. The onset, intensity and duration of these signs will be recorded (if appropriate). Control animals will be similarly examined for comparison.

15.3. Body Temperature

Frequency: Pretreatment – once; Dosing Period – Day 1, 4 hours post dose (±1 hour) and 24 hours post dose (±1 hour).

Day 22, pre-dose (this may be collected the day before), 4 hours post dose (±1 hour) and 24 hours post dose (±1 hour).

Procedure: The rectal temperature of 10 male and 10 female main study animals will be recorded.

15.4. Body Weights

Frequency: Once pretreatment, on each dosing Day (Days 1, 22 and 43) and 3 days after the first and second dosing occasion (i.e. Days 2-4, 23-25) and for two days after the third dosing occasion (i.e. Day 44-45) Twice weekly during non-dosing weeks.

Procedure: Animals will be individually weighed. A weight will be recorded on each day of scheduled necropsy.

15.5. Food Consumption

Frequency: Once during pretreatment
Day 1, Day 22, Day 43 (i.e. Days 1-2, 22-23 and 43-44). Twice weekly during non-dosing weeks.

Procedure: Food consumption will be quantitatively measured.

15.6. Dermal Scoring

Frequency: Each dosing occasion: Predose, 4 h post dose, then daily until any reaction is resolved and at termination.

Procedure: Skin will be assessed for erythema and eschar formation, oedema formation and any other reaction to treatment.

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15.7. ~~Modified~~ Irwin Screen Observations

On Days 8 and 29, the first six males per group (main study animals) will be observed and the following parameters will be included in the observations:

Occurrence of vocalisation, stereotypies, aggressiveness, abnormal gait, straub tail, abducted hind limbs, tremor, twitches, convulsions, body posture, sedation, catalepsy, ptosis, exophthalmos, salivation, lacrimation, piloerection, abnormal respiration, defecation, urination and death.

Increase or decrease of spontaneous activity, touch response and body tonus. Increase of sniffing, grooming, scratching and rearing.

Decreased pinna reflex, traction response and grip strength. Any additional symptoms observed will also be noted.

Frequencies of animals exhibiting symptoms will be recorded. Symptoms will be scored from 0 to 3, where 0 represent no findings and 3 the highest score.

Pupil size will be measured using a guidance chart to estimate the size in millimetres.

Body temperature will be measured by using a probe inserted approx. 2 cm past the anal sphincter. At least 30 minutes prior to the commencement of observations, to reduce measurement variability, a temperature habituation trial will be conducted by inserting the temperature probe, however, no temperature data will be collected during this trial.

15.7.1. Apparatus

The traction response will be measured by assessing the ability of mice to pull themselves up onto a cage top.

Grip strength will be assessed by allowing mice to grip onto the cage lid. Hold the mouse and let it grip onto the grid with all paws and then gently pull the mouse backwards from the lid.

A proforma with a size scale will be used for assessing relative pupil sizes only and no exact sizes will be calculated or implied.

A thermometer, with a flexible probe, will be used to measure body temperature.

16. LABORATORY EVALUATIONS

16.1. Clinical Pathology

16.1.1. Blood Sample Collection

Blood will be collected from the orbital sinus under non-recoverable isoflurane anaesthesia, in ascending animal order unless samples are collected prior to necropsy where the order of euthanasia will be followed. Animals will not be fasted.

After collection, samples will be transferred to the appropriate laboratory for processing.

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Samples will be collected according to the following table.

Samples for Clinical Pathology Evaluation

Group Nos.	Time Point	Haematology	Plasma Chemistry
First 10 numbered Main Study animals per sex per group	Day 45	X	-
Second 10 numbered Main Study animals per sex per group		-	X
First 10 numbered Recovery animals per sex per group	Day 74	X	-
Second 10 numbered Recovery animals per sex per group		-	X
Unscheduled euthanasia of whole group (when possible)	Before euthanasia	X	X

X = sample to be collected; - = not applicable. Individual premature decedents will not be sampled.

Any residual/retained clinical pathology samples will be discarded following approval of the results by Charles River Clinical Pathology Department, and before issue of the Final Report.

16.1.2. Haematology

Target Volume: 0.3 mL

Anticoagulant: K_2EDTA

Haematology Parameters

Red blood cell count Haemoglobin Haematocrit Mean corpuscular volume Mean corpuscular haemoglobin concentration Mean corpuscular haemoglobin Reticulocytes (%) Reticulocyte count (absolute)	Red blood cell distribution width Platelet count White blood cell count Neutrophil count (absolute) Lymphocyte count (absolute) Monocyte count (absolute) Eosinophil count (absolute) Basophil count (absolute) Large unstained cells Blood Smear (see ^ below)

^ A blood smear will be prepared from each haematology sample. Blood smears will be labelled, stained, and stored. Individual blood smears may be examined to confirm certain analyser results, as required by SOP.

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If additional examination of blood smears is deemed necessary, the smears may be subsequently evaluated and this evaluation will be described in a protocol amendment.

Morphology findings that require confirmation, as required by SOP, will be reviewed by a clinical pathologist in Charles River.

16.1.3. Plasma Chemistry

Target Volume: As much as possible (no more than 1.0 mL required)

Anticoagulant: Lithium Heparin

Processing: To plasma

Plasma Chemistry Parameters

Aspartate aminotransferase	Triglycerides
Alanine aminotransferase	Phosphate
Alkaline phosphatase	Calcium
Glutamate dehydrogenase	Total Bile Acids
Total protein	Sodium
Albumin	Potassium
Globulin	Chloride
Total bilirubin[a]	Albumin/globulin ratio
Urea	Lipaemia (visual qualitative assessment)
Creatinine	Icterus (visual qualitative assessment)
Cholesterol	Haemolysis (Visual Qualitative Assesment)
Glucose	

[a] When total bilirubin is >8.55µmol/L, indirect and direct bilirubin will also be measured

16.1.4. Bone Marrow Smear Evaluation

Bone marrow smears will be collected as described in the Tissue Collection and Preservation table (Section 17.5). Evaluation of stained smears may be added by amendment at the discretion of the Study Director in consultation with the pathologist and the Sponsor.

16.2. Immunogenicity Evaluation

16.2.1. Immunogenicity Sample Collection

Blood will be collected from the saphenous vein of all immunogenicity animals using a suitably sized needle.

Samples will be collected on the following occasions.

Pretreatment, Day 22 (before dosing), Day 43 (before dosing) and Day 74 (at termination).

Target Volume: 0.2 mL

Anticoagulant: None (serum separator tubes)

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16.2.2. Immunogenicity Sample Processing

Samples will be allowed to clot at ambient temperature for at least 60 minutes before centrifugation. The samples will be centrifuged at 1500 *x* g for 10 min in a centrifuge set to 4°C and the resultant serum will be separated, transferred to uniquely labelled clear polypropylene tubes, and frozen immediately over dry ice before being transferred and stored in a freezer set to maintain -80°C.

Serum tube labelling: All serum samples will be marked with the study number, animal number, group number and experimental day number.

Samples will be shipped after Day 22, 43 and 74 on dry ice to the following address.

Shipping Contact

The analytical laboratory will be notified before shipment of the samples. Upon receipt at the bioanalytical laboratory, the samples will be stored in a freezer set to maintain -80°C.

16.2.3. Immunogenicity Sample Analysis

Sample analysis; Immunogenicity will be performed by AZ and supplied to CRL as tabulated data. Interpretation of this data within the main report will be performed by a scientist at the Test Facility, s 22

The full details of the immunogenicity bioanalysis method are included in the Phase Plan and a copy of the Phase Plan is included in Attachment 1. The individual data will be reported in the phase report which will be included as an appendix to the main report and the interpretation of the data and summary data tables will be included in the main report.

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17. TERMINAL PROCEDURES

Terminal procedures are summarised in the following table:

Terminal Procedures for Main Study and Recovery Animals

Group Number	Number of Animals		Scheduled Euthanasia Day	Necropsy Procedures			Histology[b]	Histopathology[b]
	M	F		Necropsy	Tissue Collection	Organ[a] Weights		
1	20	20	45 (main study)	X	X	X	Full Tissue or Blocks only[c]	Full Tissue[d]
2	20	20					Full Tissue or Blocks only[c]	Full Tissue[d]
1	20	20	74 (recovery)	X	X	X	Full Tissue or Blocks only[c]	Full Tissue[d]
2	20	20					Full Tissue or Blocks only[c]	Full Tissue[d]
Unscheduled Deaths				X	X	-	Full Tissue	Full Tissue

X = procedure to be conducted; - = not applicable; Block = processed tissue to wax cassette.
[a] See Tissue Collection and Preservation table for listing of weights.
[b] See Tissue Collection and Preservation table for listing of tissues.
[c] Tissues from the remaining 10 animals will be processed to wax block and stored pending possible future evaluation, which will be documented in a protocol amendment, if required.
[d] Only tissues from the first 10 animals/sex/group will be evaluated histopathologically.

17.1. Unscheduled Deaths

If a main study or recovery animal dies on study or is killed for humane reasons, a necropsy will be conducted and specified tissues will be saved. If necessary, the animal will be refrigerated to minimise autolysis.

Main study or recovery animals may be euthanised for humane reasons as per Test Facility SOPs. The body weight will be recorded and samples for evaluation of clinical pathology parameters (if an entire group of animals are euthanised) will be obtained if possible as specified in Section 16. These animals will undergo necropsy, and specified tissues will be retained. If necessary, the animal will be refrigerated to minimise autolysis.

Immunogenicity animals that die on study or are euthanised for humane reasons will have blood sample collected for immunogenicity analysis as specified in Section 16. The animal will be subjected to necropsy examination as detailed in Section 17.3 and tissues will be retained without evaluation. If required, evaluation will be documented in a protocol amendment.

17.2. Scheduled Euthanasia

Main study and recovery animals surviving until scheduled euthanasia will have a terminal body weight recorded, and will be euthanised by exposure to a rising concentration of carbon dioxide followed by exsanguination. When possible, the animals will be euthanised in a rotating order

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across dose groups such that similar numbers of AZD1222 and control animals will be necropsied throughout the day. Animals will not be fasted before their scheduled necropsy.

Immunogenicity animals surviving until scheduled euthanasia will be euthanised by an approved method. No necropsy will be performed and no tissues will be collected.

17.3. Necropsy

Main and recovery animals will be subjected to a complete necropsy examination, which will include evaluation of the carcass and musculoskeletal system; all external surfaces and orifices; cranial cavity and external surfaces of the brain; and thoracic, abdominal, and pelvic cavities with their associated organs and tissues. Macroscopic abnormalities will be recorded. Necropsy examinations will be conducted by a trained technician and will consist of an external and internal examination and recording of observations for all animals. A veterinary pathologist will be available for consultation during normal working hours.

At the discretion of the necropsy supervising pathologist, images may be generated for illustration of or consultation on gross observations. Generation of such images will be documented and communicated to the Study Director. Images and associated documentation will be retained and archived.

Any remaining tissues not required for histopathology or retention may be harvested from the carcass of control animals before disposal. These tissues, if collected, may be used for validation or investigational purposes and as such are not part of this study.

17.4. Organ Weights

The organs identified for weighing in the Tissues Collection and Preservation table will be weighed at necropsy (unless otherwise specified) for all scheduled euthanasia animals. Organ weights will not be recorded for animals found dead or euthanised in poor condition or in extremis. Paired organs will be weighed together. In the event of gross abnormalities, in addition to the combined weight, the weight of each organ of a pair may be taken and entered as a tissue comment. Terminal body weights will be used for organ weight analysis.

17.5. Tissue Collection and Preservation

Representative samples of the tissues identified in the Tissue Collection and Preservation table will be collected from all animals and preserved in 10% neutral buffered formalin, unless otherwise indicated. Additional tissue samples may be collected to elucidate abnormal findings.

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Tissue Collection and Preservation

Tissue	Weigh	Collect	Microscopic Evaluation	Comment
Administration site 1	-	X	X	Left thigh
Administration site 2	-	X	X	Right thigh
Animal identification	-	X	-	-
Artery, aorta	-	X	X	From thoracic segment.
Bone marrow smear	-	X	-	Two bone marrow smears will be collected from the femur at scheduled and unscheduled necropsies (for possible examination). Smears will not be collected from animals that are found dead or from animals that were euthanised moribund and then stored in the refrigerator prior to necropsy. Bone marrow smears are allowed to air dry and are fixed in Methanol.
Bone marrow, sternum	-	X	X	Collect with bone, sternum.
Bone, femur	-	X	X	Collect distal end to include femorotibial joint.
Bone, sternum	-	X	X	-
Brain	X	X	X	Eight brain levels to be examined to include caudal part of olfactory bulb (Bolon sections). Olfactory bulbs (OB) to be severed from the brain at necropsy and left to fix in the skull with calvarium removed; OB removed from skull at trimming for processing and embedding.
Cervix	-	X	X	Collect with uterus.
Epididymis x 2	X	X	X	Preserve in Modified Davidson's fixative.
Eye x 2	-	X	X	Preserve in Davidson's fixative.
Gallbladder	-	X	X	Collected and weighed with liver.
Ganglion Dorsal Root	-	X	-	Collected with vertebral column. The vertebral column will be trimmed at histology for the ganglion dorsal root.
Gland, adrenal x 2	X	X	X	-
Gland, harderian x 2	-	X	X	-
Gland, mammary	-	X	X	Collect with inguinal skin. Examine in males only if present on routine section of inguinal skin.
Gland, parathyroid x 2	-	X	X	Collect with gland, thyroid. Examine only if present in the routine section of gland, thyroid.
Gland, pituitary	X	X	X	-
Gland, prostate	X	X	X	-
Gland, salivary x2	-	X	X	Mandibular.
Gland, salivary x2	-	X	X	Parotid.
Gland, seminal vesicle	-	X	X	Left and right horns.
Gland, thyroid x2	-	X	X	-
Gross lesions/masses	-	X	X	Include local draining lymph nodes to masses.
Heart	X	X	X	-
Hindlimb x 2	-	X	-	The right and left hindlimb, including the foot, will be collected after removal of other tissues from this and the surrounding area.
Kidney x 2	X	X	X	-

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Tissue	Weigh	Collect	Microscopic Evaluation	Comment
Large intestine, caecum	-	X	X	-
Large intestine, colon	-	X	X	-
Large intestine, rectum	-	X	X	-
Liver	X	X	X	-
Lung	X	X	X	Infuse with 10% neutral buffered formalin after weighing. If a lung infection is suspected at necropsy, diagnostic tissue samples should be taken for bacteriology.
Lymph node, inguinal	-	X (2)	X	Left and right nodes.
Lymph node, mandibular	-	X	X	-
Lymph node, mesenteric	-	X	X	-
Muscle, skeletal	-	X	X	From gastrocnemius.
Nerve, optic x 2	-	X	X	Preserve in Davidson's fixative. Examine only if present in the routine section of the eye.
Nerve, sciatic	-	X	X	-
Oesophagus	-	X	X	-
Ovary x 2	X	X	X	-
Oviduct x 2	-	X	X	Collect with uterus.
Pancreas	-	X	X	-
Skin	-	X	X	Collect with gland, mammary
Small intestine, duodenum	-	X	X	-
Small intestine, ileum	-	X	X	Including Peyer's Patch
Small intestine, jejunum	-	X	X	-
Spinal cord	-	X	X	Cervical, thoracic and lumbar in situ.
Spleen	X	X	X	-
Stomach	-	X	X	Glandular and non-glandular regions.
Testis x 2	X	X	X	Preserve in Modified Davidson's fixative.
Thymus	X	X	X	-
Tongue	-	X	X	-
Trachea	-	X	X	-
Ureter x 2	-	X	X	-
Urinary bladder	-	X	X	Distend contracted bladders by infusing with 10% neutral buffered formalin.
Uterus	X	X	X	-
Vagina	-	X	X	-

X = procedure to be conducted; - = not applicable.

18. HISTOLOGY AND HISTOPATHOLOGY

18.1. Histology

Tissues in the Tissue Collection and Preservation table from animals identified in the Terminal Procedures table will be embedded in paraffin, sectioned, mounted on glass slides, and stained with haematoxylin and eosin.

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18.2. Histopathology

Histopathological evaluation will be performed by a veterinary pathologist with training and experience in laboratory animal pathology. Tissues identified as target tissues will be examined from animals identified in the Terminal Procedures table, by protocol amendment. Any additional stains or evaluations, if deemed necessary by the pathologist, will be added by protocol amendment following discussion with the Study Director and in consultation with the Sponsor.

At the discretion of the study pathologist and after acknowledgement by the study director, images may be captured for illustration of or consultation on histological observations. These illustration images will not be used for data generation or interpretation and will not be archived or included in the Final Report.

18.3. Pathology Peer Review

An external pathology peer review, according to the Sponsors' standard operating procedures, will be conducted by an AstraZeneca Peer Reviewing Pathologist at Astra Zeneca. The review will not claim GLP compliance.

All slides will be scanned at 40 X using a Leica Aperio ScanScope® AT2 Slide Scanning System to generate Whole Slide Images (WSI) according to the relevant Charles River Edinburgh SOPs. Peer review will be undertaken by the sponsor peer review pathologist using the WSI scans accessed through the Charles River Laboratories server (Leica eSlide Manager®) and reviewed using the associated web viewer. All WSI files may also be copied to an external drive and shipped to the peer review pathologist at the address above.

The peer review statement or equivalent documentation will be included as an appendix to the Final Report.

19. COMPUTERISED SYSTEMS

The following critical computerised systems may be used in the study. Any additional critical computerised systems used during the course of the study will be added by protocol amendment. The actual critical computerised systems used will be specified in the Final Report.

Data for parameters not required by protocol, which are automatically generated by analytical devices used will be retained on file but not reported. Statistical analysis results that are generated by the program but are not required by protocol and/or are not scientifically relevant will be retained on file but will not be included in the tabulations.

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Critical Computerised Systems

System Name	Description of Data Collected and/or Analysed
Dispense	Test item receipt, accountability and/or formulation activities
Provantis	Applicable in-life, clinical pathology and postmortem
MSD Analysis	Immunogenicity
MSD SECTOR S 600	Immunogenicity
In-house reporting software Nevis (using SAS)	Applicable in-life, clinical pathology and postmortem
Deviation Information Library	Deviations
Vaisala/Trend 963 Secure	Continuous temperature and humidity recording. Alarms for animal rooms, refrigerators, freezers and incubators.
Share Document Management System	Reporting
Docusign	Collection of CFR Part 11 compliant signature
eSlide manager version 12.4.3.7006	Histopathology Peer Review

20. DATA AND STATISTICAL ANALYSIS

20.1. Irwin Data Analysis

Frequencies of mice exhibiting a given symptom will be reported in tabulated form. Severity scores of the observed symptoms will be measured in four categories (0, 1, 2, or 3) and will be presented as the dose group mean of the maximal possible score [MPS=score/max score*100] for each mouse at each time point. MPS will be displayed graphically for symptoms with statistically significant findings.

Observations such as death and seizures will always be considered significant regardless of frequency. For all other symptoms the statistical analysis will be performed using SAS v9.4 (or a later version) as follows:

1. Severity score will be modelled as a categorical outcome (0, 1, 2, or 3) and will be compared between Group 2 and Group 1 using a two-sided Fisher's exact test at a significance level of 20% (no multiple testing correction).

20.2. Statistical Analysis

Unless otherwise stated, all statistical tests will be two-sided and performed at the 5% significance level. Males and females will be analysed separately. Where data are collected at repeated time points, each time point will be analysed separately.

Pairwise comparisons will only be performed against the control group (Group 1). The following pairwise comparisons will be performed:

Control Group v Group 2

Body weight, food consumption, pupil size, absolute organ weights and organ weights as a percentage of terminal body weight will be analysed using a parametric ANOVA. Pairwise comparisons will be made using Dunnett's t test if the overall F-test is significant (provided there

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are 3 groups to compare). Datasets with two groups will be compared using a Dunnett's test (equivalent to t-test in Nevis 2012 tables).

Haematology and plasma chemistry will be analysed using a Kruskal-Wallis nonparametric ANOVA. Pairwise comparisons will be made using Dunn's test if the overall Kruskall-Wallis test is significant.

In the ANOVA summary tables, the results of the analysis will be reported indicating the level of statistical significance ($p \leq 0.05$, $p \leq 0.01$ and $p \leq 0.001$) of each pairwise comparison.

Actual p-values will not be reported in the summary tables for these analyses.

More extensive analysis will be carried out only after consultation with the sponsor and will involve additional costs.

21. AMENDMENTS AND DEVIATIONS

Changes to the approved protocol shall be made in the form of an amendment, which will be signed and dated by the Study Director. Every reasonable effort will be made to discuss any necessary protocol changes in advance with the Sponsor.

All protocol and SOP deviations will be documented in the study records. Deviations from the protocol and/or SOP related to the phase(s) of the study conducted at a Test Site shall be documented, acknowledged by the PI, and reported to the Study Director for authorisation/acknowledgement. The Study Director will notify the Sponsor of deviations that may result in a significant impact on the study as soon as possible.

22. RETENTION OF RECORDS, SAMPLES AND SPECIMENS

All study-specific raw data, electronic data, documentation, protocol, protocol amendments, retained samples and specimens, and interim (if applicable) and final reports generated by Charles River from this study will be transferred to a Charles River archive. Three years after issue of the final report, the Sponsor will be contacted to determine the disposition of materials associated with the study. The original signed copy of the final report will be archived indefinitely at the Test Facility.

Records to be maintained will include, but will not be limited to, documentation and data for the following:

- Protocol, protocol amendments, and deviations
- Study schedule
- Study-related correspondence
- Test system receipt, health, and husbandry
- Test and control item receipt, identification, preparation, and analysis
- In-life measurements and observations

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- Clinical pathology sample collection and evaluation
- Immunogenicity sample collection
- Gross and microscopic observations and related data
- Whole Slide Image (WSI) Electronic Files generated by Leica Aperio ScanScope® AT2 Slide Scanning System
- Organ weight measurements
- Statistical analysis results

23. REPORTING

A comprehensive Draft Report and Toxicology AZ/CTD tabulated summary will be prepared following completion of the study and will be finalised following consultation with the Sponsor. The report will include all information necessary to provide a complete and accurate description of the experimental methods and results and any circumstances that may have affected the quality or integrity of the study.

The Sponsor will receive an electronic version of the Draft and Final Report provided in Adobe Acrobat PDF format (Acrobat Versions 5 or 6 hyperlinked and searchable at final) along with a Microsoft Word version of the text. The PDF document will be created from native electronic files to the extent possible, including text and tables generated by the Test Facility. Report components not available in native electronic files and/or original signature pages will be scanned and converted to PDF image files for incorporation. A signed copy of the final report will be retained at the Test Facility.

Special attention will be paid to the following:

All fonts must be embedded

Book marks and cross-references are created using Inherit Zoom and not Named Destinations

The PDF file is not “tagged”

Reports should be finalised within 6 months of issue of the audited Draft Report. If the Sponsor has not provided comments to the report within 6 months of draft issue, the report will be finalised by the Test Facility unless other arrangements are made by the Sponsor.

23.1. SEND Datasets

At the request of the Sponsor, SEND datasets will be generated and provided outside the context of the Final GLP Report. These datasets will not be subject to QA Audit nor will they be used as the basis for the Study Director interpretation of the study results. SEND datasets will be provided following the Draft and/or Final Report.

Appendix 1

24. ANIMAL WELFARE

The UK Home Office controls scientific procedures on animals in the UK and does so by the issue of licences under the Animals (Scientific Procedures) Act 1986. The regulations conform to EU Directive 2010/63/EU and achieve the standard of care required by the US Department of Health and Human Services' Guide for the Care and Use of Laboratory Animals.

The Home Office licence governing this study strictly specifies the limits of severity of effects on the animals. From the available information, the procedures described in the protocol are not anticipated to cause any effects which exceed the severity limit of the procedure. Any animal which shows unacceptable reactions may be killed or other actions taken as required by the Home Office to alleviate distress.

24.1. Home Office Project Licence No.

PBAD559F8, Toxicology of Pharmaceuticals, Protocol No. 1.

From 04 Nov 2020, the licence will change to PP7137579, Protocol 2.

Appendix 1

REFERENCES

1. s 22 (On going). ChAdOx1-nCovd19: A Preliminary Intramuscular Injection Vaccine Development and Reproductive Study in Female CD-1 Mice. Charles River Study No. 490838.

Appendix 1

AMENDMENT APPROVAL

Study Director

Appendix 1

SPONSOR APPROVAL

Not required.

Appendix 1

ATTACHMENTS

Attachment 1 - PHASE PLAN

Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

PHASE PLAN

AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

Immunogenicity Bioanalysis

Study Number: 513351

AstraZeneca Phase Number:

2020-AZD1222-0217

Final v1.0

20-Nov-2020

Sponsor:
AstraZeneca R&D Cambridge
da Vinci Building
Melbourn Science Park
Cambridge Road
Melbourn
Hertfordshire SG8 6HB

Test Site:
Integrated Bioanalysis
AstraZeneca
Aaron Klug Building
Granta Park
Cambridge
CB21 6GH

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Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

CONTACT DETAILS

Study Director:

Address:

Telephone No.

Email:

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Address:

Telephone No

Email:

Sponsor Address:

AstraZeneca R&D Cambridge
da Vinci Building
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Appendix 1

Test Site Identifier: 2020-AZD1222-0217
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1 ABBREVIATIONS

Non-standard abbreviations listed.

AAPS	American Association of Pharmaceutical Scientists
Au	Arbitrary Units
BCC	Back Calculated Concentration
CCD	Charge Coupled Device
CDER	Centre for Drug Evaluation and Research
CV (%)	Co-efficient of Variation (Precision)
DPBS	Dulbecco's Phosphate Buffered Saline
ECL	Electrochemiluminescence
EMA	European Medicines Agency
EFD	Embryofetal Development
EU	European Union
FDA	Food and Drug Administration
FT	Freeze/thaw
GLP	Good Laboratory Practice
GLP & RQA	GLP & Research Quality Assurance
HQC	High Quality Control
ID	Identification
IgG	Immunoglobulin G
LQC	Low Quality Control
LLOQ	Lower Limit of Quantification

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Ltd	Limited
MQC	Mid Quality Control
N/A	Not Applicable
MRD	Minimum Required Dilution
MSD	Meso Scale Discovery
OECD	Organisation for Economic Co-operation and Development
PBS	Phosphate Buffered Saline
QC	Quality Control
% RE	Relative Error
TPA	Tripropylamine
SOP	Standard Operating Procedure
Std	Calibration Standard
Std Dev	Standard Deviation
UK	United Kingdom
ULOQ	Upper Limit of Quantification
USA	United States of America
Vol	Volume
WS	Working Stock

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2 INTRODUCTION

2.1 Phase Objectives

The purpose of this bioanalytical phase is the detection of IgG antibodies against SARS-CoV-2 spike protein in murine serum samples, following administration of ChAdOx1-nCovd-19 (AZD1222) within study 513351; a 6 week intermittent dosing intramuscular vaccine toxicity study in the mouse with a 4 week recovery. The Test Facility for Study 513351 is Charles River Laboratories Edinburgh Ltd, UK. AZD1222 is under development by AstraZeneca as a potential COVID-19 vaccine.

The immunogenicity method to be used in this bioanalytical phase was validated under Test Site study number 2020-AZD1222-0213, with a further partial validation under 2020-AZD1222-0227. Method development was documented in lab book 8245-20.

2.2 Immunogenicity Assay Context of Use

AZD1222 is a vaccine against COVID-19 and encodes the spike protein of the SARS-CoV-2 coronavirus. The purpose of the assay is in support of murine toxicology studies to demonstrate seroconversion of animals against the SARS-CoV-2 spike protein following immunisation with AZD1222. The assay is a relative-quantitative immunoassay in murine serum performed on the MSD platform, using a monoclonal antibody against the SARS-CoV-2 spike protein as calibrator. Data from the assay will be used to demonstrate exposure in the animals to the vaccine and seroconversion against the spike protein.

Antibody levels are expected to change in fold-level increases following prime and prime boost immunisations and as such the acceptance criteria specified for assay parameters in this plan are deemed appropriate for the defined context of use.

2.3 GLP Compliance

This phase of the study will be conducted in compliance with the OECD Principles of GLP (ENV/MC/CHEM) (98)17 (1997), as implemented at the national level in the UK GLP Regulations, Statutory Instrument 3106 (1999), as amended by Statutory Instrument 994 (Codification Amendments Etc.) (2004). This phase will also be conducted to current Standard Operating Procedures.

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Test Site Identifier: 2020-AZD1222-0217
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2.4 Quality Assurance

Test Site QA will review the phase plan and audit the final phase report. At AstraZeneca the GLP & Research Quality Assurance (GLP & RQA) department fulfils the role of QA as defined in the UK GLP regulations. GLP & RQA will conduct phase specific audits, however, process-based audits may also be utilised or used in place of phase specific audits. The findings of any audits carried out in this phase will be reported promptly to the PI, Test Site Management, the Study Director, Test Facility Management and Lead QA. The types of audits conducted, and the dates of inspection and reporting will be specified in a Quality Assurance statement, for inclusion in the final bioanalytical phase report.

3 PHASE SCHEDULE

Proposed Experimental Starting Date:	Week Commencing 23-Nov-2020
Proposed Experimental Completion:	Week Commencing 23-Nov-2020
Proposed Date of audited Final Report:	23-Dec-2020

4 MATERIALS

4.1 Critical Reagents

4.1.1 Anti-SARS-CoV-2 Antibody - Calibrator

Company Code/Name:	CV191074 Murine IgG2a
Concentration:	1.17 mg/mL
Lot Number:	CV191074-003 (BET280820)
Re-test Date:	Assigned 27-Oct-2022
Storage Conditions:	Nominally -80°C
Source:	AstraZeneca Biologics Expression Team Cambridge, UK

4.1.2 SARS-CoV-2 Trimeric Spike Protein

SARS-CoV-2 Trimeric spike protein (to be termed 'Trimer') will be supplied by Biopharmaceutical Development, AstraZeneca. Trimer will be assigned a retest date and

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stored at nominally -80°C. Full details including lot number will be recorded in the raw data and final report.

4.1.3 Detection Antibody

SULFO-TAG labelled goat anti-mouse antibody will be supplied by MSD (product number: R32AC-1) and stored at 2 to 8°C. Full details including lot number and expiry date will be recorded in the raw data and final report.

4.1.4 Control Biological Matrix

Pooled mouse serum samples will be supplied as required by an appropriate vendor, with required safety information, and stored in a freezer set at -80°C. Full details of batch numbers and expiry dates will be recorded in the raw data and final phase report.

4.2 Other Reagents

4.2.1 MSD 96 Well High Bind Plates

MSD 96 well high bind plates (product number: L15XB) will be obtained from MSD and stored as per manufacturer's instructions at room temperature. Batch numbers and expiry dates will be documented in the raw data and final phase report.

4.2.2 Blocker Casein in PBS (Assay Diluent)

Blocker Casein in PBS (Assay Diluent) (product number: 37528) will be obtained from Thermo Fisher Scientific and stored as per manufacturer's instructions at 2 to 8°C. Batch numbers and expiry dates will be documented in the raw data and final phase report.

4.2.3 MSD® Gold Read Buffer B

Read Buffer B (product number: R60AM) will be supplied by MSD® and stored as per manufacturer's instructions at room temperature. Batch numbers and expiry dates will be documented in the raw data and final phase report.

4.2.4 Tween 20

Tween 20 (product number: P2287-500ML) will be supplied by Sigma-Aldrich Company Ltd, UK and stored as per manufacturer's instructions at room temperature. Batch numbers and expiry dates will be documented in the raw data.

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4.2.5 Phosphate Buffered Saline (PBS) Tablets

PBS tablets (product number: BR0014G) will be supplied by OXOID and stored as per manufacturer's instructions at room temperature. Batch numbers and expiry dates will be documented in the raw data.

4.2.6 Dulbecco's Phosphate Buffered Saline

Dulbecco's Phosphate Buffered Saline (product number: 14190-086) will be obtained from Thermo Fisher Scientific and stored as per manufacturer's instructions at room temperature. Batch numbers and expiry dates will be documented in the raw data.

4.3 Critical Analytical Equipment and Validated Software

Equipment	Description
MSD SECTOR S 600	MSD, asset number: 200034966, serial number: 1201150625310
MSD Analysis Software	Discovery Workbench 4.0.12

A full list of equipment used will be kept in the phase file and key equipment will be detailed in the final report.

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5 METHOD

5.1 Analytical Procedure

For the method a sequential direct format ECL immunoassay is used. MSD high-bind microtitre plates are coated with recombinant spike protein trimer from SARS-CoV-2 which captures any anti-SARS-CoV-2 immunoglobulins present in the calibrators, QC, and test samples. IgG is then detected using a SULFO-TAG-labelled goat anti-mouse antibody to form an immune complex. The complex is then detected by the addition of MSD Read Buffer to the plate and subsequent excitation of the SULFO-TAG label. The quantity of light detected correlates to the level of anti-SARS-CoV-2 IgG present in the sample.

A full description of the assay procedure is presented in Appendix 1 (Section 10) with assay proforma in Appendix 2 (Section 11).

5.2 Preparation of Reagents

The preparation of reagents necessary for the assay are included in the assay procedure in Appendix 1 (Section 10). All volumes may be scaled as appropriate. Exact preparation details will be recorded in the raw data.

5.3 Preparation of Calibration Standards

Anti-SARS-CoV-2 calibration standard curve will be prepared in mouse serum as detailed in Table 5.3-1.

Table 5.3-1 Preparation of Calibration Standards

Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	ID	Concentration (ng/mL)**
CV191074 (1.17 mg/mL)	10	81.4	Std1	128000
Std1	30	30	Std2	64000
Std2	30	30	Std3	32000*
Std3	30	30	Std4	16000
Std4	30	30	Std5	8000
Std5	30	30	Std6	4000
Std6	30	30	Std7	2000
Std7	30	30	Std8	1000
Std8	30	30	Std9	500
Std9	30	30	Std10	250*
Std10	30	30	Std11	125

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Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	ID	Concentration (ng/mL)**
N/A	N/A	30	Blank	0.00

*Limits of quantification **Calculation rounded to 3 significant figures

Volumes may be scaled up or down as required.

5.4 Preparation of Quality Control (QC) Samples

Anti-SARS-CoV-2 quality control (QC) samples will be prepared by spiking the CV191074 calibrator antibody (Section 4.1.1) into mouse serum as detailed in Table 5.4-1. The QC samples will be assigned a batch number and expiry date and aliquoted and stored in a freezer set at -80°C.

Validation controls prepared within method partial validation (2020-AZD1222-0227) may also be reassigned as QCs for this analytical phase.

Table 5.4-1 Preparation of Quality Controls

Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	Concentration (ng/mL)	ID
CV191074 (1.17 mg/mL)	36	1720	24000	HQC
HQC	200	1400	3000	MQC
HQC	40	1495	625	LQC

Volumes may be scaled up or down as required. Calculations rounded to 3 significant figures

5.5 Final Preparation of Standards, Controls and Samples

All standards, QC, and study samples will be subject to a 100-fold minimum required dilution (MRD) in assay diluent (Blocker Casein in PBS) prior to analysis. Exact preparation details will be documented in the raw data.

5.6 Study Sample Preparation

All study samples will undergo the 100-fold MRD. Where required, samples may be diluted up to and including a further 800-fold in 1% murine serum. Samples will first undergo the 100-Fold MRD with subsequent dilutions post-MRD prepared by diluting in 1% murine serum. All samples will be tested in duplicate (n=2 replicates).

The exact dilution factor that will be required to obtain an acceptable result for each sample is unknown thus it may be necessary to simultaneously analyse samples at multiple dilutions. This is to manage limited sample volume and to ensure a valid result is obtained.

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Should multiple dilutions result in more than one acceptable determination, the result reported will be the result obtained from the lowest dilution factor.

5.7 Data Processing and Analysis

All data collection, processing and storage will be performed using the software detailed in Section 4.3 and Microsoft Excel. Full details of software used will be recorded in the phase file and final report.

The calibration curve fit will be a 4 parameter fit with $1/y^2$ weighting.

QC and Calibration Standard data will be reported to the nearest whole number in ng/mL. All test sample concentration data will be reported to 3 decimal places in AU/mL following a conversion factor of 0.001 (where AU = arbitrary units).

All precision (% CV) and accuracy (% RE) data will be reported to one decimal place.

6 ACCEPTANCE CRITERIA FOR ANALYTICAL BATCHES

6.1 Acceptance Criteria for Calibration Standards

Standard curve precision (% CV) and accuracy (% RE) must fulfil the following criteria; a minimum of 75% of the calibration standards (minimum of six non-zero standards within the working range) should have a precision of ≤ 30% CV and an accuracy of ±≤ 30% RE. Anchor points are not subject to these criteria. All standards will be analysed in duplicate (n=2). Accuracy will be assessed using the following equation:

% RE = [(Observed Value – Nominal Concentration)/Nominal Concentration)] x 100

Precision will be assessed using the following equation:

% CV = (Std Dev of Mean Calculated Concentration/Mean Calculated Concentration) x100

6.2 Acceptance Criteria for QCs

Acceptance criteria for QC samples are based on precision and accuracy and should fulfil the following conditions:

Precision and accuracy is deemed acceptable if at least 66.7% (4 out of 6) of all QC samples within a run and 50% at each concentration level demonstrate precision of ≤ 30% CV and accuracy of ±≤ 35% RE.

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6.3 Acceptance Criteria for Analytical Assay Runs

A standard curve and two sets of each QC level will be included in each analytical run and will be run in duplicate (n=2). The analytical run will be accepted when conditions detailed in Section 6.1 and 6.2 are met.

6.4 Acceptance Criteria for Samples

Acceptance criteria for measurement of the samples will be a precision for the determined concentration of SARS-CoV-2 antibodies of ≤ 30% CV between replicates. Determined sample concentrations (following dilution) must be within the calibration range of 250 ng/mL to 32000 ng/mL. Precision acceptance criteria will not be applied to any samples where both replicates fall below the limit of quantification (BLQ). Only data from accepted analytical assay runs will be reported.

7 SAMPLES

7.1 Sample Receipt

Samples are expected as per the Study Protocol for 513351. Samples will be stored in a freezer set to maintain -80°C upon receipt and will be logged in as per SOP CT-030023. Full details of shipments will be recorded in the raw data and the final phase report.

7.2 Analysis of Study Samples

All murine serum samples will be measured using the validated method.

Samples should undergo no more than the 2 FT cycles. During analysis samples should be retained at room temperature for the minimum time possible; the positive control anti-SARS-CoV-2 antibody has been demonstrated to be stable in murine serum stored at room temperature for at least 24 hours.

The stability of immunoglobulins in serum when stored at -80°C is well documented in the literature and as such long-term stability assessment is not being conducted.

7.3 Disposal of Study Samples

Sample storage and disposal procedures will be carried out in accordance with SOP CT-030023 and the protocol for Study 513351.

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Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

8 REPORTING

The final phase report will include, but not necessarily be limited to, the following:

- Analytical Study Title (Including Study Number and Test Site Identifier)
- Name and Address of Study Sponsor, Test Facility and Principal Investigator
- Actual Experimental Start and Completion Dates
- Compliance Statement for respective stage of the Phase Report
- Key Personnel
- Test Guidance and Recommendations
- Introduction
- Experimental Details to Include: Materials, Methods, Data Processing, Reagents, Preparation of Standards and Controls, Mode of Analysis and Calculations, Acceptance/Rejection Criteria and Statistical Methods
- Results and Discussion
- Tabular and Graphical Data Presentation where appropriate
- Statistical Analysis Summary
- Record Retention Statement
- Example Standard Curve

Appendix 1

Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

9 STANDARD OPERATING AND ARCHIVING PROCEDURES

9.1 Standard Operating Procedures

This phase will be conducted according to AstraZeneca Standard Operating Procedures.

9.2 Maintenance of Records

Records of all test measurements, analyses and events that relate to the phase will be maintained in the phase file and associated data files. Electronic records of raw and processed data files associated with the phase will be maintained on the AstraZeneca GLP file share until such time that they are backed-up according to SOP IT-030097.

Upon completion of the analytical phase, records (paper and electronic) will be archived according to SOP RM-030071. All physical raw data and phase related documents generated during the course of the phase, including a copy of the phase plan and report, will be stored initially in the archive at AstraZeneca, Milstein Building, Granta Park, Cambridge, CB21 6GH, UK. Periodically phase and non-phase specific records will be transferred to an off-site contract archive facility, Qualogy (Thrapston, Northants, NN14 4ZL, UK) for storage according to SOP RM-030071.

9.3 Phase Plan Amendments

Changes to this phase plan will be fully documented according to AstraZeneca SOP CT-030083 and archived along with the phase plan.

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Test Site Identifier: 2020-AZD1222-0217
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10 APPENDIX 1: ASSAY PROCEDURE

10.1 Reagent Preparation

10.1.1 Preparation of Capture Reagent (SARS-CoV-2 Trimeric Spike Protein)

The capture reagent will be diluted to 3.0 µg/mL in DPBS. Capture reagent should be prepared immediately prior to use.

10.1.2 Preparation of Detection Reagent

The detection reagent (SULFO-TAG labelled goat anti-mouse antibody) stock will be diluted to 1.0 µg/mL in assay diluent (Blocker Casein in PBS). Detection reagent should be prepared immediately prior to use.

10.1.3 Preparation of 0.1% Tween 20 in PBS Wash Buffer

2 L of 0.1% Tween 20 in PBS Wash Buffer will be made from 20 PBS Tablets, plus 2.0 mL Tween 20 in 2 L lab grade water (volumes can be scaled up or down). The expiry date will be one week from date of preparation.

10.1.4 Preparation of 1% Matrix

Pooled mouse serum (100% matrix) will be diluted to 1% matrix in assay diluent (Blocker Casein in PBS).

10.1.5 Preparation of Read Buffer B

MSD Gold Read Buffer B will be neat used as supplied.

10.2 Preparation of Samples and Controls

All samples and controls will be subject to the 100-fold MRD in assay diluent (Blocker Casein in PBS) prior to analysis.

Where required, samples may undergo further dilution in 1% murine serum, as detailed in Section 5.6.

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Test Site Identifier: 2020-AZD1222-0217
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10.3 Assay Procedure

Procedure		Performed by: Initial/date
1.	Coat MSD 96 well high bind plate with 25 µL per well of Trimer at 3 µg/mL in DPBS. Seal the plate and incubate overnight at 2-8°C.	Step 1
2.	Wash the plate 3x with 300 µL per well of Wash Buffer and blot dry. Block plate with 150 µL per well of Blocker Casein in PBS, seal the plate and incubate for at least 30 minutes on a plate shaker set at 25°C and shaking at 700 rpm. Incubation Start Time:_____ Incubation End Time:_____ Total Incubation Time:_____ Shaker ID:_____ Washer ID:_____	Steps 2 to 5
3.	Wash the plate 3x with 300 µL per well of Wash Buffer and blot dry. Add 50 µL per well of calibration or QC/test sample to the plate. Seal the plate and incubate on a plate shaker set at 25°C and shaking at 700 rpm for 120 ± 10 minutes. Incubation Start Time:_____ Incubation End Time:_____ Total Incubation Time:_____ Shaker ID:_____ Washer ID:_____	
4.	Wash the plate 3x with 300 µL per well of Wash Buffer and blot dry. Add 50 µL per well of Detection Reagent. Seal the plate and incubate on a plate shaker set at 25°C and shaking at 700 rpm for 60 ± 5 minutes. Incubation Start Time:_____ Incubation End Time:_____ Total Incubation Time:_____ Shaker ID:_____ Washer ID:_____	
5.	Wash the plate 3x with 150 µL per well of Wash Buffer and blot dry. Add 150 µL per well of Read Buffer B and read on MSD S 600 within 10 minutes. Time Read Buffer added:_____ Time Plate Read:_____ Total Time:_____ Washer ID:_____	

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Test Site Identifier: 2020-AZD1222-0217
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11 APPENDIX 2: ASSAY PROFORMA

Date:	Project/Molecule:
Study Number:	Assay Number:
Assay Content:	

Reagent Details

MSD 96 Well High Bind Plate (Product No. L15XB)	Batch Number: Expiry Date: Barcode ID:
Matrix (Pooled mouse serum)	Batch Number: Expiry Date:
Positive Control (CV191074)	Batch Number: Expiry Date:
Capture Reagent (Trimer)	Batch Number: Expiry Date:
Detection Reagent (Product No. R32AC-1)	Batch Number: Expiry Date:
Blocking Agent & Assay Diluent (Blocker Casein in PBS, Product No. 37528)	Batch Number: Expiry Date:
Read Buffer (Read Buffer B, R60AM)	Batch Number: Expiry Date:
Wash Buffer (0.1% Tween 20 in PBS)	Batch Number: Expiry Date:
Other Reagents	
Pipette IDs	

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Study Number: 513351

Run Number:	

Working Reagent Preparation

Reagent ID	Preparation Details	Prepared by (Sign/date)
Capture Reagent	Stock Concentration: _____ mg/mL Final Working Concentration: _____ µg/mL Preparation: _____ µL Stock + _____ µL DPBS	
Detection Reagent	Stock Concentration: _____ µg/mL Final Working Concentration: _____ µg/mL Preparation: _____ µL Stock + _____ µL Assay Diluent	
1% Matrix	Neat Matrix (Pooled Mouse Serum): 100% Final Working Concentration: 1% Preparation: _____ µL Serum + _____ µL Assay Diluent	
Calculations Checked by:		

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Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

Run Number:	

Calibrator:	Anti-SARS-CoV-2 spike antibody Identifier: CV191074 Lot: Expiry:

Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	ID	Concentration (ng/mL)	Prepared by (Sign/date)
CV191074 (1.17 mg/mL)	10	81.4	Std1	128000	
Std1	30	30	Std2	64000	
Std2	30	30	Std3	32000	
Std3	30	30	Std4	16000	
Std4	30	30	Std5	8000	
Std5	30	30	Std6	4000	
Std6	30	30	Std7	2000	
Std7	30	30	Std8	1000	
Std8	30	30	Std9	500	
Std9	30	30	Std10	250	
Std10	30	30	Std11	125	
N/A	N/A	30	Blank	0.00	

QC Sample Details

Batch Number: Retest Date:		
IDs and Concentrations:	HQC: 24000 ng/mL MQC: 3000 ng/mL LQC: 625 ng/mL	Confirmed by (Sign/date)

Appendix 1

Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

Sample Preparation and MRD

Sample Details	Prepared by (Sign/date)
Minimum Required Dilution	
1 in 100 MRD: 10 µL in 990 µL Assay Diluent	
Calculations Checked by:	

Appendix 1

Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

Run Number:	

Assay Result: Pass/Fail
Comments:
Deviations noted:
Deviations Acknowledged by PI (Sign/Date)

Number of Attachments:.....

Analyst:..... Date:.....

Checked by:..... Date:.....

Appendix 1

charles river

FINAL PROTOCOL

Test Facility Study No. 513351

Sponsor Reference No. 1156PM

AstraZeneca Project Name: AZD1222

AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

SPONSOR:
AstraZeneca R&D Cambridge
da Vinci Building
Melbourn Science Park
Cambridge Road
Melbourn
Hertfordshire SG8 6HB
UK

TEST FACILITY
Charles River Laboratories Edinburgh Ltd
Elphinstone Research Centre
Tranent, East Lothian
EH33 2NE
UK

Appendix 1

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1. OBJECTIVE(S)

AZD1222 is a recombinant, replicant defective adenovirus (ChAdOx1 nCov-19) expressing the SARS-CoV-2 spike (S) surface glycoprotein which is under development by AstraZeneca as a potential COVID-19 disease prevention vaccine. The objective of this study is to determine the potential toxicity of AZD1222 when given by intramuscular injection intermittently (on Days 1, 22 and 43) to mice with a minimum 28 day recovery period to evaluate the potential reversibility of any findings. In addition the antibody response will be evaluated.

1.1. Study Classification

Study Category:	Toxicology
Study Type:	Repeat Dose Toxicity
Study Design:	Parallel
Primary Treatment CAS Registry Number:	Not Available
Primary Treatment Unique Ingredient ID:	Not Available
Class of Compound:	Not Available

2. PROPOSED STUDY SCHEDULE

Proposed study dates are listed below. Actual applicable dates will be included in the Final Report.

Experimental Start Date:	01 Sep 2020 (First date of study-specific data collection)
Experimental Completion Date:	Jan 2021 (Last date data are collected from the study)
Animal Arrival/Transfer:	25 Aug 2020
Initiation of Dosing:	08 Sep 2020
Completion of In-life:	
Main Study:	22 Oct 2020
Recovery:	20 Nov 2020 (Dates of necropsy)
Immunogenicity Sample Despatch:	Delivery 1: 30 Sep 2020 Delivery 2: 21 Oct 2020 Delivery 3: 23 Nov 2020
Clinical Pathology Review (Main Study):	05 Nov 2020 (10 business days from first necropsy)
Clinical Pathology Review (Recovery):	04 Dec 2020 (10 business days from last necropsy)
Audited Draft Immunogenicity Report:	To be added by amendment

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Irwin Measurements Draft Report:	15 Dec 2020 (50 business days from the Day 29 Irwin measurement)
Main Study Pathology Draft Report and Slides Available for Sponsor Peer Review:	27 Nov 2020 (32 business days from first necropsy)
Full Pathology Draft Report (including recovery) and Slides Available for Sponsor Peer Review:	24 Dec 2020 (24 business days from last necropsy)
Pathology Draft Report after Sponsor Peer Review:	19 Jan 2021 (38 business days from last necropsy)
Unaudited Draft Report:	28 Jan 2021 (45 business days from last necropsy)
Receipt of Sponsor Comments:	11 Feb 2021 (55 business days from last necropsy)
Audited Draft Report:	25 Feb 2021 (65 business days from last necropsy)
Finalization of Phase Reports and final set of Sponsor Comments:	04 Mar 2021 (70 business days from last necropsy)
Final Report:	11 Mar 2021 (75 business days from last necropsy) (Expected date of Study Director signature)

3. GUIDELINES FOR STUDY DESIGN

The design of this study was based on the study objective(s), the overall product development strategy for the test item, and the following study design guidelines:

- ICH Harmonised Tripartite Guideline S7A. *Guideline on Safety Pharmacology Studies for Human Pharmaceuticals*.
- Committee for Medicinal Products for Human Use (CHMP). *Note for Guidance on Repeated Dose Toxicity*. CPMP/SWP/1042/99rev1.
- ICH Harmonised Tripartite Guideline M3 (R2). *Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals.*
- WHO Guideline on Nonclinical Evaluation of Vaccines, Nov 2005, and WHO Guideline on the Nonclinical Evaluation of Vaccine Adjuvants and Adjuvanted vaccines Oct 2013.
- FDA: Guideline for Industry: Considerations for Development Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications 2006, and Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry; Center for Biologics Evaluation and Research; June 2020.
- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Number 13. *Consensus Document of the Working Group on Good Laboratory Practice. The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies*.

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4. REGULATORY COMPLIANCE

This study will be performed in accordance with the OECD Principles of Good Laboratory Practice as incorporated into the United Kingdom Statutory Instrument for GLP and as accepted by Regulatory Authorities throughout the European Union, United States of America (FDA and EPA) and Japan (MHLW, MAFF and METI), and other countries that are signatories to the OECD Mutual Acceptance of Data Agreement.

Exceptions to GLP include the following:

- Pathology Peer Review

5. QUALITY ASSURANCE

5.1. Test Facility

The Test Facility Quality Assurance Unit (QAU) will monitor the study to assure the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with Good Laboratory Practice regulations. The QAU will review the protocol, conduct inspections at intervals adequate to assure the integrity of the study, and audit the Final Report to assure that it accurately describes the methods and standard operating procedures and that the reported results accurately reflect the raw data of the study.

The Test Facility QAU contact for this study is indicated below:

s 22

5.2. Sponsor

The conduct of the following study phase(s) will be audited by the Sponsor QAU(s):

- Immunogenicity

Inspections will be 'to be added by amendment' based and performed per Test Site SOP. For all study phases inspected by Sponsor or Sponsor subcontractor QAU(s), copies of each periodic inspection report will be made available to the Study Director, Test Facility Management and Test Facility QAU.

6. COMMUNICATION

The Study Director will send an electronic version of the study plan (Final Protocol) and any amendments (signed by the Study Director and, when applicable, Test Facility Management) to the Sponsor Representative (Study Monitor), Alternative Sponsor Contact, Clinical Pathology Reviewer (if applicable), s 22 and to each Monitoring Scientist.

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7. SPONSOR

Sponsor Representative (Study Monitor)

s 22

Alternative Sponsor Contact

s 22

8. RESPONSIBLE PERSONNEL

Study Director

s 22

Management Contact

s 22

Clinical Pathology Review

s 22

Individual Scientists (IS) at Test Facility

Pathology

s 22

Appendix 1

Irwin Measurements s 22

Each IS is required to report any deviations or other circumstances that could affect the quality or integrity of the study to the Study Director in a timely manner. Each IS will provide a report addressing their assigned phase of the study, which will be included as an appendix to the Final Report. The phase report will include the following:

- A listing of critical computerised systems used in the conduct and/or interpretation of the assigned study phase

Principal Investigators (PI) at Test Site

Immunogenicity s 22

The PI's reference number for this phase of the study will be added by amendment.

Each PI is required to report any deviations or other circumstances that could affect the quality or integrity of the study to the Study Director in a timely manner. Each PI will provide a report addressing their assigned phase of the study, which will be included as an appendix to the Final Report. A draft of the phase report will be submitted to the Study Director for review prior to finalisation. The phase report will include the following:

- A Statement of Compliance
- A QA Statement
- The archive site for all records, samples, specimens and reports generated from the phase or segment (alternatively, details regarding the retention of the materials may be provided to the Study Director for inclusion in the Final Report)
- A listing of critical computerised systems used in the conduct and/or interpretation of the assigned study phase

Monitoring Scientist (MS) at AstraZeneca

Pathology s 22

Appendix 1

Irwin Observations

Clinical Pathology

9. TEST AND CONTROL ITEMS

9.1. Test Item(s)

Identification: AZD1222

Alternative Identification: ChAdOx1-nCovd-19

Supplier: To be added by amendment

Batch (Lot) Number: To be added by amendment

Batch Release Date: To be added by amendment

Expiration Date: To be added by amendment

Viral Particle Concentration: 5.33x10^11/mL

Storage Conditions: In a freezer at approximately -80°C.

Administration Dose Form: Solution

9.2. Control Item Components

Identification: To be added by amendment

Composition: 10 mM histidine, 7.5% (v/w) sucrose, 35 mM sodium chloride, 1 mM magnesium chloride, 0.1% (v/w) Polysorbate-80, 0.1 mM EDTA and 0.5% (v/w) ethanol, pH 6.6, in water for injection

Appendix 1

Supplier:	To be added by amendment
Batch (Lot) Number:	To be added by amendment
Expiration Date:	To be added by amendment
Storage Conditions:	In a freezer at approximately -80°C.

9.3. Test and Control Item Characterisation

The Sponsor will provide to the Test Facility documentation of the identity, strength, purity, composition and stability for the test item. A Test Item (Compound) Characterisation Summary (TICS) and Test formulation Summary (TFS) or equivalent documentation will be provided for retention in the raw data.

The Sponsor has appropriate documentation on file concerning the method of synthesis, fabrication or derivation of the test and control item(s), and this information is available to the appropriate regulatory agencies should it be requested.

9.4. Analysis of Test Item

The stability of the bulk test item will not be determined during the course of this study. Information to support the stability of each lot of the bulk test item will be provided by the Sponsor.

9.5. Reserve Samples

A reserve sample will not be retained at the Test Facility as the Sponsor has indicated that they will retain a reserve sample.

9.6. Test and Control Item Inventory and Disposition

Records of the receipt, distribution, and storage of test and control items will be maintained. The quantity of test item/control item remaining will be communicated to the Study Monitor, who will decide if it should be discarded or returned to the Sponsor.

Shipping Contact

10. SAFETY

Safety instructions for this study are provided on the Sponsor supplied safety data sheet. COSHH assessment and classification will be carried out at the Test Facility on a Chemical Classification Spreadsheet.

Appendix 1

11. DOSE FORMULATION AND ANALYSIS

11.1. Preparation of Control Item

The control item, to be added by amendment, will be dispensed as required. The control item will be removed from the freezer on the morning of dosing and delivered to the animal unit on 'wet' ice. On arrival at the animal unit, dosing vials will be allowed to reach room temperature before dosing.

Thawed vials cannot be re-frozen or re-used and will be disposed of after being used for dosing formulation preparation.

Any residual volumes will be discarded unless otherwise requested by the Study Director.

11.2. Preparation of Test Item

The test item, AZD1222, will be administered as received. The required number of vials will be removed from the freezer on the morning of dosing and delivered to the animal unit on 'wet' ice. On arrival at the animal unit, dosing vials will be allowed to reach room temperature before dosing.

Thawed vials cannot be re-frozen or re-used and will be disposed of after use.

Any residual volumes will be discarded unless otherwise requested by the Study Director.

11.3. Sample Collection and Analysis

The test and control items will be used as received from the Sponsor; therefore, samples for dose formulation analysis will not be collected by the Test Facility.

12. TEST SYSTEM

Species:	Mouse
Strain:	CD-1 Crl:CD-1 (ICR)
Condition:	Purpose-bred, naive
Source:	Charles River UK Limited, Margate, Kent, UK
Number of Males Ordered:	88 (including 3 extras)
Number of Females Ordered:	88 (including 3 extras)
Target Age at the Initiation of Dosing:	7-8 weeks
Target Weight at the Initiation of Dosing:	20-40 g

The actual age and weight of animals will be listed in the Final Report.

12.1. Justification of Test System and Number of Animals

The mouse was chosen as the animal model for this study as it is a rodent species accepted by regulatory agencies for toxicity testing.

Appendix 1

The total number of animals to be used in this study is considered to be the minimum required to properly characterise the effects of the test item. This study has been designed such that it does not require an unnecessary number of animals to accomplish its objectives.

12.2. Animal Identification

At study assignment, each animal will be identified using a subcutaneously implanted electronic cylindrical, 'glass-sealed' TROVAN microchip.

12.3. Environmental Acclimation

The animals will be allowed to acclimate to the Test Facility rodent toxicology accommodation for a period of up to 3 weeks (minimum of one week) before the commencement of dosing.

12.4. Selection, Assignment, Replacement and Disposition of Animals

Males and females will be randomised separately.

Cages will be racked by dose group and arranged vertically throughout the rack. Control animals will be housed on a separate rack.

Before the initiation of dosing, any assigned animals considered unsuitable for use in the study will be replaced by alternative animals obtained from the same shipment and maintained under the same environmental conditions.

After initiation of dosing, study animals may be replaced during the replacement period with alternative animals in the event of accidental injury, non-test item-related health issues, or similar circumstances.

The alternative animals may be used as replacements on the study within 3 days.

The disposition of all animals will be documented in the study records.

13. HUSBANDRY

13.1. Housing

Males will be housed individually and females will be housed 2 or 3 per cage (unless reduced by mortality) in solid bottom polyethermide plastic cages with wire bar lid.

Bedding material will be sterilised white wood shavings which will be provided with a certificate of analysis for significant contaminants. An analytical certificate for each batch of bedding used will be retained at the Test Facility.

There are no known contaminants in the bedding that would interfere with the objectives of the study.

13.2. Environmental Conditions

The targeted conditions for animal room environment will be as follows:

Temperature: 19 - 23°C

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Humidity:	40 - 70%
Ventilation:	A minimum of 10 air changes per hour
Light Cycle:	12 hours light and 12 hours dark (except when interrupted by study procedures/activities)

There will be automatic control of temperature and humidity which will be continuously monitored and recorded. Information on actual temperature and humidity ranges versus target ranges will be presented in the study report.

The light cycle will be controlled automatically.

13.3. Food

SDS Rat and Mouse No. 1 Diet SQC Expanded will be provided *ad libitum* throughout the study, except during designated procedures. The same diet in meal form may be provided to individual animals as warranted by clinical signs (e.g. broken/damaged incisors or other health changes).

The feed is analysed by the supplier for nutritional components and environmental contaminants. Results of the analysis are provided by the supplier and will be retained at the Test Facility.

There are no known contaminants in the feed that are considered to interfere with the objectives of the study.

13.4. Water

The animals will have access to water *ad libitum* from the public supply from water bottles which will be changed as necessary throughout the course of the study.

The water used by the Test Facility is analysed at regular intervals for dissolved materials, heavy metals, pesticide residues, pH, nitrates and nitrites. Microbiological screening is also conducted. An analytical certificate for each analysis will be retained at the Test Facility.

The water used is considered not to contain any additional substances, in sufficient concentration, to have any influence on the outcome of the study.

13.5. Animal Enrichment

For psychological/environmental enrichment, males will be provided with items such as a device for hiding in and an object for chewing, except when interrupted by study procedures/activities.

Females will be socially housed for psychological/environmental enrichment and will be provided with items such as a device for hiding in and an object for chewing, except when interrupted by study procedures/activities.

Objects for chewing and devices for hiding in will be provided with a certificate of analysis for significant contaminants. An analytical certificate for each batch of chewing objects and devices for hiding used will be retained at the Test Facility.

Appendix 1

Other items may be included to enrich the cage environment. Details will be given in the study report.

13.6. Veterinary Care

Veterinary care will be available throughout the course of the study and animals will be examined by the veterinary staff as warranted by clinical signs or other changes. All veterinary examinations and recommended therapeutic treatments, if any, will be documented in the study records.

In the event that animals show signs of illness or distress, the responsible veterinarian may make initial recommendations about treatment of the animal(s) and/or alteration of study procedures, which must be approved by the Study Director or by Test Facility management if the Study Director is not available, except where detailed below where immediate action is required to address a potentially life-threatening situation, or to alleviate acute severe pain. All such actions will be documented in the study records and, when appropriate, by protocol amendment. Treatment of the animal(s) for minor injuries or ailments may be approved without prior consultation with the Sponsor representative when such treatment does not impact fulfilment of the study objectives. If the condition of the animal(s) warrants significant therapeutic intervention or alterations in study procedures, the Sponsor representative will be contacted, when possible, to discuss appropriate action. If the condition of the animal(s) is such that emergency measures must be taken, the Study Director and/or attending veterinarian will attempt to consult with the Sponsor representative prior to responding to the medical crisis, but the Study Director and/or veterinarian has authority to act immediately at his/her discretion to alleviate suffering. The Sponsor representative will be fully informed of any such events.

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14. EXPERIMENTAL DESIGN

Experimental Design

Group No.	Animal Numbers					
	Main Study		Recovery		Immunogenicity	
	Males	Females	Males	Females	Males	Females
1	1001-1020	1501-1520	1101-1120	1601-1620	-	-
2	2001-2020	2501-2520	2101-2120	2601-2620	2201-2205	2701-2705

Extra animals will be numbered 3001-3003M and 3501-3503F
- = Not applicable

Group No.	Dose Volume[a] (µL)	Total Viral Particle (VP)/dose	Viral Particle (VP) Concentration per 1 mL
1	70	0	0
2	70	3.73×10^{10}	5.33x10^11

[a] 35 µL will be administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

14.1. Administration of Test and Control Items

The test or control items will be administered to the appropriate animals by intramuscular injection (dose split across two dose sites) on Days 1, 22 and 43. The first day of dosing will be designated as Day 1. The dosing formulations will be allowed to reach room temperature before administration. Animals will generally be dosed during the morning.

The doses will be given using a graduated syringe and sterile hypodermic needle (details of the gauge and type of needle used will be retained in the raw data).

Each hindlimb will receive 0.035 mL, total dose of 0.07 mL.

Left hindlimb = Site 1

Right hindlimb = Site 2

The administration sites will be clipped free of hair before the first injection. The injection site will be marked. Further clipping and marking will occur as necessary to maintain visibility of each site.

14.2. Recovery Period

On completion of the dosing period, the designated recovery animals will be retained for a minimum 28 day recovery period.

14.3. Justification of Route and Dosage Levels

The intramuscular injection route of administration has been selected for this study as this route has been defined by the Sponsor as the route of clinical application.

Appendix 1

Regulatory guidelines indicate that the highest proposed clinical dose should be evaluated in the animal model, and an additional dose included (n+1). For this vaccine the clinical dose is not expected to exceed 5x10^10 virus particles/dose with the number of dosing occasions being 2. However, as the dose is limited by the volume that can be administered by intramuscular injection to mice, the maximum feasible dose of 3.73x10^10 virus particles will be given. On a body weight basis, this exceeds the human exposure by >1000x, assuming 50 kg human and 50 g mouse. Previous data generated for the Sponsor indicated that 1.7x10^10 virus particles/dose in mice induced an appropriate immune response. Charles River Study No. 490838 [1] has shown that 2.6x10^10/dose produced no in-life adverse signs of toxicity.

15. IN-LIFE PROCEDURES, OBSERVATIONS, AND MEASUREMENTS

15.1. Mortality/Moribundity Checks

Frequency: Twice daily, once at the start and once towards the end of the working day throughout the study.

Procedure: Animals will be observed for general health/mortality and moribundity. Animals will not be removed from the cage during observation, unless necessary for identification or confirmation of possible findings.

15.2. Clinical Observations

15.2.1. Detailed Clinical Observations

Frequency: Weekly, beginning Week -1.

Procedure: Animals removed from the cage for examination.

15.2.2. Pre and Post dose Observations

Frequency: Regularly throughout the day on dosing days. On non-dosing days, signs will be recorded at least once.

Procedure: All the animals will be examined for reaction to AZD1222. The onset, intensity and duration of these signs will be recorded (if appropriate). Control animals will be similarly examined for comparison.

15.3. Body Temperature

Frequency: Pretreatment – once; Dosing Period – Day 1, 4 hours post dose (±1 hour)

Procedure: The rectal temperature of 10 male and 10 female main study animals will be recorded.

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15.4. Body Weights

Frequency:	Once pretreatment, on each dosing Day (Days 1, 22 and 43) and 3 days after the first and second dosing occasion (i.e. Days 2-4, 23-25) and for two days after the third dosing occasion (i.e. Day 44-45) Twice weekly during non-dosing weeks.
Procedure:	Animals will be individually weighed. A weight will be recorded on each day of scheduled necropsy.

15.5. Food Consumption

Frequency:	Once during pretreatment Day 1, Day 22, Day 43 (i.e. Days 1-2, 22-23 and 43-44). Twice weekly during non-dosing weeks.
Procedure:	Food consumption will be quantitatively measured.

15.6. Dermal Scoring

Frequency:	Each dosing occasion: Predose, 4 h post dose, then daily until any reaction is resolved and at termination.
Procedure:	Skin will be assessed for erythema and eschar formation, oedema formation and any other reaction to treatment.

15.7. Modified Irwin Screen Observations

On Days 8 and 29, the first six males per group (main study animals) will be observed and the following parameters will be included in the observations:

Occurrence of vocalisation, stereotypies, aggressiveness, abnormal gait, straub tail, abducted hind limbs, tremor, twitches, convulsions, body posture, sedation, catalepsy, ptosis, exophthalmos, salivation, lacrimation, piloerection, abnormal respiration, defecation, urination and death.

Increase or decrease of spontaneous activity, touch response and body tonus. Increase of sniffing, grooming, scratching and rearing.

Decreased pinna reflex, traction response and grip strength. Any additional symptoms observed will also be noted.

Frequencies of animals exhibiting symptoms will be recorded. Symptoms will be scored from 0 to 3, where 0 represent no findings and 3 the highest score.

Pupil size will be measured using a guidance chart to estimate the size in millimetres.

Body temperature will be measured by using a probe inserted approx. 2 cm past the anal sphincter. At least 30 minutes prior to the commencement of observations, to reduce measurement variability, a temperature habituation trial will be conducted by inserting the temperature probe, however, no temperature data will be collected during this trial.

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15.7.1. Apparatus

The traction response will be measured by assessing the ability of mice to pull themselves up onto a cage top.

Grip strength will be assessed by allowing mice to grip onto the cage lid. Hold the mouse and let it grip onto the grid with all paws and then gently pull the mouse backwards from the lid.

A proforma with a size scale will be used for assessing relative pupil sizes only and no exact sizes will be calculated or implied.

A thermometer, with a flexible probe, will be used to measure body temperature.

16. LABORATORY EVALUATIONS

16.1. Clinical Pathology

16.1.1. Blood Sample Collection

Blood will be collected from the orbital sinus under non-recoverable isoflurane anaesthesia, in ascending animal order unless samples are collected prior to necropsy where the order of euthanasia will be followed. Animals will not be fasted.

After collection, samples will be transferred to the appropriate laboratory for processing.

Samples will be collected according to the following table.

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Samples for Clinical Pathology Evaluation

Group Nos.	Time Point	Haematology	Plasma Chemistry
First 10 numbered Main Study animals per sex per group	Day 45	X	-
Second 10 numbered Main Study animals per sex per group		-	X
First 10 numbered Recovery animals per sex per group	Day 74	X	-
Second 10 numbered Recovery animals per sex per group		-	X
Unscheduled euthanasia of whole group (when possible)	Before euthanasia	X	X

X = sample to be collected; - = not applicable. Individual premature decedents will not be sampled.

Any residual/retained clinical pathology samples will be discarded following approval of the results by Charles River Clinical Pathology Department, and before issue of the Final Report.

16.1.2. Haematology

Target Volume: 0.3 mL

Anticoagulant: K_2EDTA

Haematology Parameters

Red blood cell count Haemoglobin Haematocrit Mean corpuscular volume Mean corpuscular haemoglobin concentration Mean corpuscular haemoglobin Reticulocytes (%) Reticulocyte count (absolute)	Red blood cell distribution width Platelet count White blood cell count Neutrophil count (absolute) Lymphocyte count (absolute) Monocyte count (absolute) Eosinophil count (absolute) Basophil count (absolute) Large unstained cells Blood Smear (see ^ below)

^ A blood smear will be prepared from each haematology sample. Blood smears will be labelled, stained, and stored. Individual blood smears may be examined to confirm certain analyser results, as required by SOP.

If additional examination of blood smears is deemed necessary, the smears may be subsequently evaluated and this evaluation will be described in a protocol amendment.

Appendix 1

Morphology findings that require confirmation, as required by SOP, will be reviewed by a clinical pathologist in Charles River.

16.1.3. Plasma Chemistry

Target Volume: As much as possible (no more than 1.0 mL required)

Anticoagulant: Lithium Heparin

Processing: To plasma

Plasma Chemistry Parameters

Aspartate aminotransferase Alanine aminotransferase Alkaline phosphatase Glutamate dehydrogenase Total protein Albumin Globulin Total bilirubin[a] Urea Creatinine Cholesterol Glucose	Triglycerides Phosphate Calcium Total Bile Acids Sodium Potassium Chloride Albumin/globulin ratio Lipaemia (visual qualitative assessment) Icterus (visual qualitative assessment) Haemolysis (Visual Qualitative Assesment)
[a] When total bilirubin is >8.55µmol/L, indirect and direct bilirubin will also be measured	

16.1.4. Bone Marrow Smear Evaluation

Bone marrow smears will be collected as described in the Tissue Collection and Preservation table (Section 17.5). Evaluation of stained smears may be added by amendment at the discretion of the Study Director in consultation with the pathologist and the Sponsor.

16.2. Immunogenicity Evaluation

16.2.1. Immunogenicity Sample Collection

Blood will be collected from the saphenous vein of all immunogenicity animals using a suitably sized needle.

Samples will be collected on the following occasions.

Pretreatment, Day 22 (before dosing), Day 43 (before dosing) and Day 74 (at termination).

Target Volume: 0.2 mL

Anticoagulant: None

16.2.2. Immunogenicity Sample Processing

Samples will be allowed to clot at ambient temperature for at least 60 minutes before centrifugation. The samples will be centrifuged at 1500 *x* g for 10 min in a centrifuge set to 4°C and the resultant serum will be separated, transferred to uniquely labelled clear polypropylene

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tubes, and frozen immediately over dry ice before being transferred and stored in a freezer set to maintain -80°C.

Serum tube labelling: All serum samples will be marked with the study number, animal number, group number and experimental day number.

Samples will be shipped after Day 22, 43 and 74 on dry ice to the following address.

Shipping Contact

The analytical laboratory will be notified before shipment of the samples. Upon receipt at the bioanalytical laboratory, the samples will be stored in a freezer set to maintain -80°C.

16.2.3. Immunogenicity Sample Analysis

To be added by amendment

Appendix 1

17. TERMINAL PROCEDURES

Terminal procedures are summarised in the following table:

Terminal Procedures for Main Study and Recovery Animals

Group Number	Number of Animals		Scheduled Euthanasia Day	Necropsy Procedures			Histology[b]	Histopathology[b]
	M	F		Necropsy	Tissue Collection	Organ[a] Weights		
1	20	20	45 (main study)	X	X	X	Full Tissue or Blocks only[c]	Full Tissue[d]
2	20	20					Full Tissue or Blocks only[c]	Full Tissue[d]
1	20	20	74 (recovery)	X	X	X	Full Tissue or Blocks only[c]	Full Tissue[d]
2	20	20					Full Tissue or Blocks only[c]	Full Tissue[d]
Unscheduled Deaths				X	X	-	Full Tissue	Full Tissue

X = procedure to be conducted; - = not applicable; Block = processed tissue to wax cassette.
[a] See Tissue Collection and Preservation table for listing of weights.
[b] See Tissue Collection and Preservation table for listing of tissues.
[c] Tissues from the remaining 10 animals will be processed to wax block and stored pending possible future evaluation, which will be documented in a protocol amendment, if required.
[d] Only tissues from the first 10 animals/sex/group will be evaluated histopathologically.

17.1. Unscheduled Deaths

If a main study or recovery animal dies on study or is killed for humane reasons, a necropsy will be conducted and specified tissues will be saved. If necessary, the animal will be refrigerated to minimise autolysis.

Main study or recovery animals may be euthanised for humane reasons as per Test Facility SOPs. The body weight will be recorded and samples for evaluation of clinical pathology parameters (if an entire group of animals are euthanised) will be obtained if possible as specified in Section 16. These animals will undergo necropsy, and specified tissues will be retained. If necessary, the animal will be refrigerated to minimise autolysis.

Immunogenicity animals that die on study or are euthanised for humane reasons will have blood sample collected for immunogenicity analysis as specified in Section 16. The animal will be subjected to necropsy examination as detailed in Section 17.3 and tissues will be retained without evaluation. If required, evaluation will be documented in a protocol amendment.

17.2. Scheduled Euthanasia

Main study and recovery animals surviving until scheduled euthanasia will have a terminal body weight recorded, and will be euthanised by exposure to a rising concentration of carbon dioxide followed by exsanguination. When possible, the animals will be euthanised in a rotating order across dose groups such that similar numbers of AZD1222 and control animals will be necropsied throughout the day. Animals will not be fasted before their scheduled necropsy.

Appendix 1

Immunogenicity animals surviving until scheduled euthanasia will be euthanised by an approved method. No necropsy will be performed and no tissues will be collected.

17.3. Necropsy

Main and recovery animals will be subjected to a complete necropsy examination, which will include evaluation of the carcass and musculoskeletal system; all external surfaces and orifices; cranial cavity and external surfaces of the brain; and thoracic, abdominal, and pelvic cavities with their associated organs and tissues. Macroscopic abnormalities will be recorded. Necropsy examinations will be conducted by a trained technician and will consist of an external and internal examination and recording of observations for all animals. A veterinary pathologist will be available for consultation during normal working hours.

At the discretion of the necropsy supervising pathologist, images may be generated for illustration of or consultation on gross observations. Generation of such images will be documented and communicated to the Study Director. Images and associated documentation will be retained and archived.

Any remaining tissues not required for histopathology or retention may be harvested from the carcass of control animals before disposal. These tissues, if collected, may be used for validation or investigational purposes and as such are not part of this study.

17.4. Organ Weights

The organs identified for weighing in the Tissues Collection and Preservation table will be weighed at necropsy (unless otherwise specified) for all scheduled euthanasia animals. Organ weights will not be recorded for animals found dead or euthanised in poor condition or in extremis. Paired organs will be weighed together. In the event of gross abnormalities, in addition to the combined weight, the weight of each organ of a pair may be taken and entered as a tissue comment. Terminal body weights will be used for organ weight analysis.

17.5. Tissue Collection and Preservation

Representative samples of the tissues identified in the Tissue Collection and Preservation table will be collected from all animals and preserved in 10% neutral buffered formalin, unless otherwise indicated. Additional tissue samples may be collected to elucidate abnormal findings.

Tissue Collection and Preservation

Tissue	Weigh	Collect	Microscopic Evaluation	Comment
Administration site 1	-	X	X	Left thigh
Administration site 2	-	X	X	Right thigh
Animal identification	-	X	-	-
Artery, aorta	-	X	X	From thoracic segment.

Appendix 1

Tissue	Weigh	Collect	Microscopic Evaluation	Comment
Bone marrow smear	-	X	-	Two bone marrow smears will be collected from the femur at scheduled and unscheduled necropsies (for possible examination). Smears will not be collected from animals that are found dead or from animals that were euthanised moribund and then stored in the refrigerator prior to necropsy. Bone marrow smears are allowed to air dry and are fixed in Methanol.
Bone marrow, sternum	-	X	X	Collect with bone, sternum.
Bone, femur	-	X	X	Collect distal end to include femorotibial joint.
Bone, sternum	-	X	X	-
Brain	X	X	X	Eight brain levels to be examined to include caudal part of olfactory bulb (Bolon sections). Olfactory bulbs (OB) to be severed from the brain at necropsy and left to fix in the skull with calvarium removed; OB removed from skull at trimming for processing and embedding.
Cervix	-	X	X	Collect with uterus.
Epididymis x 2	X	X	X	Preserve in Modified Davidson's fixative.
Eye x 2	-	X	X	Preserve in Davidson's fixative.
Gland, adrenal x 2	X	X	X	-
Gland, harderian x 2	-	X	X	-
Gland, mammary	-	X	X	Collect with inguinal skin. Examine in males only if present on routine section of inguinal skin.
Gland, parathyroid x 2	-	X	X	Collect with gland, thyroid. Examine only if present in the routine section of gland, thyroid.
Gland, pituitary	X	X	X	-
Gland, prostate	X	X	X	-
Gland, salivary x2	-	X	X	Mandibular.
Gland, salivary x2	-	X	X	Parotid.
Gland, seminal vesicle	-	X	X	Left and right horns.
Gland, thyroid x2	-	X	X	-
Gross lesions/masses	-	X	X	Include local draining lymph nodes to masses.
Heart	X	X	X	-
Kidney x 2	X	X	X	-
Large intestine, caecum	-	X	X	-
Large intestine, colon	-	X	X	-
Large intestine, rectum	-	X	X	-
Liver	X	X	X	-
Lung	X	X	X	Infuse with 10% neutral buffered formalin after weighing. If a lung infection is suspected at necropsy, diagnostic tissue samples should be taken for bacteriology.
Lymph node, inguinal	-	X (2)	X	Left and right nodes.
Lymph node, mandibular	-	X	X	-
Lymph node, mesenteric	-	X	X	-
Muscle, skeletal	-	X	X	From gastrocnemius.
Nerve, optic x 2	-	X	X	Preserve in Davidson's fixative. Examine only if present in the routine section of the eye.
Nerve, sciatic	-	X	X	-

Appendix 1

Tissue	Weigh	Collect	Microscopic Evaluation	Comment
Oesophagus	-	X	X	-
Ovary x 2	X	X	X	-
Oviduct x 2	-	X	X	Collect with uterus.
Pancreas	-	X	X	-
Skin	-	X	X	Collect with gland, mammary
Small intestine, duodenum	-	X	X	-
Small intestine, ileum	-	X	X	Including Peyer's Patch
Small intestine, jejunum	-	X	X	-
Spinal cord	-	X	X	Cervical, thoracic and lumbar.
Spleen	X	X	X	-
Stomach	-	X	X	Glandular and non-glandular regions.
Testis x 2	X	X	X	Preserve in Modified Davidson's fixative.
Thymus	X	X	X	-
Tongue	-	X	X	-
Trachea	-	X	X	-
Ureter x 2	-	X	X	-
Urinary bladder	-	X	X	Distend contracted bladders by infusing with 10% neutral buffered formalin.
Uterus	X	X	X	-
Vagina	-	X	X	-

X = procedure to be conducted; - = not applicable.

18. HISTOLOGY AND HISTOPATHOLOGY

18.1. Histology

Tissues in the Tissue Collection and Preservation table from animals identified in the Terminal Procedures table will be embedded in paraffin, sectioned, mounted on glass slides, and stained with haematoxylin and eosin.

18.2. Histopathology

Histopathological evaluation will be performed by a veterinary pathologist with training and experience in laboratory animal pathology. Tissues identified as target tissues will be examined from animals identified in the Terminal Procedures table, by protocol amendment. Any additional stains or evaluations, if deemed necessary by the pathologist, will be added by protocol amendment following discussion with the Study Director and in consultation with the Sponsor.

At the discretion of the study pathologist and after acknowledgement by the study director, images may be captured for consultation purposes.

18.3. Pathology Peer Review

An external pathology peer review, according to the Sponsors' standard operating procedures, will be conducted by an AstraZeneca Peer Reviewing Pathologist at Astra Zeneca. The review will not claim GLP compliance.

Slides will be dispatched to:

Appendix 1

Following completion of peer review slides will be returned to the Test Facility.

The peer review statement or equivalent documentation will be included as an appendix to the Final Report.

19. COMPUTERISED SYSTEMS

The following critical computerised systems may be used in the study. Any additional critical computerised systems used during the course of the study will be added by protocol amendment. The actual critical computerised systems used will be specified in the Final Report.

Data for parameters not required by protocol, which are automatically generated by analytical devices used will be retained on file but not reported. Statistical analysis results that are generated by the program but are not required by protocol and/or are not scientifically relevant will be retained on file but will not be included in the tabulations.

Critical Computerised Systems

System Name	Description of Data Collected and/or Analysed
Dispense	Test item receipt, accountability and/or formulation activities
Provantis	Applicable in-life, clinical pathology and postmortem
To be added by amendment	Immunogenicity
In-house reporting software Nevis (using SAS)	Applicable in-life, clinical pathology and postmortem
Deviation Information Library	Deviations
Vaisala/Trend 963 Secure	Continuous temperature and humidity recording. Alarms for animal rooms, refrigerators, freezers and incubators.
Share Document Management System	Reporting
Docusign	Collection of CFR Part 11 compliant signature

20. DATA AND STATISTICAL ANALYSIS

20.1. Irwin Data Analysis

Frequencies of mice exhibiting a given symptom will be reported in tabulated form. Severity scores of the observed symptoms will be measured in four categories (0, 1, 2, or 3) and will be presented as the dose group mean of the maximal possible score [MPS=score/max score*100] for each mouse at each time point. MPS will be displayed graphically for symptoms with statistically significant findings.

Observations such as death and seizures will always be considered significant regardless of frequency. For all other symptoms the statistical analysis will be performed using SAS v9.4 (or a later version) as follows:

Appendix 1

1. Severity score will be modelled as a categorical outcome (0, 1, 2, or 3) and will be compared between Group 2 and Group 1 using a two-sided Fisher's exact test at a significance level of 20% (no multiple testing correction).

20.2. Statistical Analysis

Unless otherwise stated, all statistical tests will be two-sided and performed at the 5% significance level. Males and females will be analysed separately. Where data are collected at repeated time points, each time point will be analysed separately.

Pairwise comparisons will only be performed against the control group (Group 1). The following pairwise comparisons will be performed:

Control Group v Group 2

Body weight, food consumption, pupil size, absolute organ weights and organ weights as a percentage of terminal body weight will be analysed using a parametric ANOVA. Pairwise comparisons will be made using Dunnett's t test if the overall F-test is significant (provided there are 3 groups to compare). Datasets with two groups will be compared using a Dunnett's test (equivalent to t-test in Nevis 2012 tables).

In the ANOVA summary tables, the results of the analysis will be reported indicating the level of statistical significance ($p \leq 0.05$, $p \leq 0.01$ and $p \leq 0.001$) of each pairwise comparison.

Actual p-values will not be reported in the summary tables for these analyses.

More extensive analysis will be carried out only after consultation with the sponsor and will involve additional costs.

21. AMENDMENTS AND DEVIATIONS

Changes to the approved protocol shall be made in the form of an amendment, which will be signed and dated by the Study Director. Every reasonable effort will be made to discuss any necessary protocol changes in advance with the Sponsor.

All protocol and SOP deviations will be documented in the study records. Deviations from the protocol and/or SOP related to the phase(s) of the study conducted at a Test Site shall be documented, acknowledged by the PI, and reported to the Study Director for authorisation/acknowledgement. The Study Director will notify the Sponsor of deviations that may result in a significant impact on the study as soon as possible.

Appendix 1

22. RETENTION OF RECORDS, SAMPLES AND SPECIMENS

All study-specific raw data, electronic data, documentation, protocol, protocol amendments, retained samples and specimens, and interim (if applicable) and final reports generated by Charles River from this study will be transferred to a Charles River archive. Three years after issue of the final report, the Sponsor will be contacted to determine the disposition of materials associated with the study. The original signed copy of the final report will be archived indefinitely at the Test Facility.

Records to be maintained will include, but will not be limited to, documentation and data for the following:

- Protocol, protocol amendments, and deviations
- Study schedule
- Study-related correspondence
- Test system receipt, health, and husbandry
- Test and control item receipt, identification, preparation, and analysis
- In-life measurements and observations
- Clinical pathology sample collection and evaluation
- Immunogenicity sample collection
- Gross and microscopic observations and related data
- Organ weight measurements
- Statistical analysis results

23. REPORTING

A comprehensive Draft Report and Toxicology AZ/CTD tabulated summary will be prepared following completion of the study and will be finalised following consultation with the Sponsor. The report will include all information necessary to provide a complete and accurate description of the experimental methods and results and any circumstances that may have affected the quality or integrity of the study.

The Sponsor will receive an electronic version of the Draft and Final Report provided in Adobe Acrobat PDF format (Acrobat Versions 5 or 6 hyperlinked and searchable at final) along with a Microsoft Word version of the text. The PDF document will be created from native electronic files to the extent possible, including text and tables generated by the Test Facility. Report components not available in native electronic files and/or original signature pages will be scanned and converted to PDF image files for incorporation. An original copy of the report with the Test Facility's handwritten signatures will be retained.

Special attention will be paid to the following:

All fonts must be embedded

Appendix 1

Book marks and cross-references are created using Inherit Zoom and not Named Destinations

The PDF file is not “tagged”

Reports should be finalised within 6 months of issue of the audited Draft Report. If the Sponsor has not provided comments to the report within 6 months of draft issue, the report will be finalised by the Test Facility unless other arrangements are made by the Sponsor.

23.1. SEND Datasets

At the request of the Sponsor, SEND datasets will be generated and provided outside the context of the Final GLP Report. These datasets will not be subject to QA Audit nor will they be used as the basis for the Study Director interpretation of the study results. SEND datasets will be provided following the Draft and/or Final Report.

24. ANIMAL WELFARE

The UK Home Office controls scientific procedures on animals in the UK and does so by the issue of licences under the Animals (Scientific Procedures) Act 1986. The regulations conform to EU Directive 2010/63/EU and achieve the standard of care required by the US Department of Health and Human Services' Guide for the Care and Use of Laboratory Animals.

The Home Office licence governing this study strictly specifies the limits of severity of effects on the animals. From the available information, the procedures described in the protocol are not anticipated to cause any effects which exceed the severity limit of the procedure. Any animal which shows unacceptable reactions may be killed or other actions taken as required by the Home Office to alleviate distress.

24.1. Home Office Project Licence No.

PBAD559F8, Toxicology of Pharmaceuticals, Protocol No. 1.

Appendix 1

REFERENCES

1. s 22 (On going). ChAdOx1-nCovd19: A Preliminary Intramuscular Injection Vaccine Development and Reproductive Study in Female CD-1 Mice. Charles River Study No. 490838.

Appendix 1

TEST FACILITY APPROVAL

The signature below indicates that Test Facility Management approves the Study Director identified in this protocol.

Test Facility Management

The signature below indicates that the Study Director approves the study protocol.

Study Director

Appendix 1

SPONSOR APPROVAL

The protocol was approved by the Sponsor by email on 24 Aug 2020. An e-mail is retained in the study raw data as proof of Sponsor protocol approval.

Appendix 1

ATTACHMENTS

None.

Appendix 2

Individual mortality

Explanation page

Abbreviation	Description
FD	Found dead
NR	Not recorded
REC	Recovery euthanasia
TE or TERM	Terminal euthanasia
UE or UNSC	Unscheduled euthanasia

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 2

Individual mortality

513351

Sex: Male Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Path Removal Reason
1001	45	22-Oct-2020	TERM
1002	45	22-Oct-2020	TERM
1003	45	22-Oct-2020	TERM
1004	45	22-Oct-2020	TERM
1005	45	22-Oct-2020	TERM
1006	45	22-Oct-2020	TERM
1007	45	22-Oct-2020	TERM
1008	45	22-Oct-2020	TERM
1009	45	22-Oct-2020	TERM
1010	45	22-Oct-2020	TERM
1011	45	22-Oct-2020	TERM
1012	45	22-Oct-2020	TERM
1013	45	22-Oct-2020	TERM
1014	45	22-Oct-2020	TERM
1015	45	22-Oct-2020	TERM

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Male Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Path Removal Reason
1016	45	22-Oct-2020	TERM
1017	45	22-Oct-2020	TERM
1018	45	22-Oct-2020	TERM
1019	45	22-Oct-2020	TERM
1020	45	22-Oct-2020	TERM

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Male Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2001	45	22-Oct-2020	-	TERM
2002	45	22-Oct-2020	-	TERM
2003	45	22-Oct-2020	-	TERM
2004	45	22-Oct-2020	-	TERM
2005	45	22-Oct-2020	-	TERM
2006	45	22-Oct-2020	-	TERM
2007	45	22-Oct-2020	-	TERM
2008	45	22-Oct-2020	-	TERM
2009	45	22-Oct-2020	-	TERM
2010	45	22-Oct-2020	-	TERM
2011	45	22-Oct-2020	-	TERM
2012	45	22-Oct-2020	-	TERM
2013	45	22-Oct-2020	-	TERM
2014	45	22-Oct-2020	-	TERM
2015	45	22-Oct-2020	-	TERM

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IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

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Sex: Male Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2016	45	22-Oct-2020	-	TERM
2017	45	22-Oct-2020	-	TERM
2018	45	22-Oct-2020	-	TERM
2019	45	22-Oct-2020	-	TERM
2020	45	22-Oct-2020	-	TERM
2201	74	20-Nov-2020	TE	-
2202	74	20-Nov-2020	TE	-
2203	74	20-Nov-2020	TE	-
2204	74	20-Nov-2020	TE	-
2205	74	20-Nov-2020	TE	-

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Path Removal Reason
1501	45	22-Oct-2020	TERM
1502	45	22-Oct-2020	TERM
1503	45	22-Oct-2020	TERM
1504	45	22-Oct-2020	TERM
1505	45	22-Oct-2020	TERM
1506	45	22-Oct-2020	TERM
1507	45	22-Oct-2020	TERM
1508	45	22-Oct-2020	TERM
1509	45	22-Oct-2020	TERM
1510	45	22-Oct-2020	TERM
1511	45	22-Oct-2020	TERM
1512	45	22-Oct-2020	TERM
1513	45	22-Oct-2020	TERM
1514	45	22-Oct-2020	TERM
1515	45	22-Oct-2020	TERM

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Path Removal Reason
1516	45	22-Oct-2020	TERM
1517	45	22-Oct-2020	TERM
1518	45	22-Oct-2020	TERM
1519	45	22-Oct-2020	TERM
1520	45	22-Oct-2020	TERM

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2501	45	22-Oct-2020	-	TERM
2502	45	22-Oct-2020	-	TERM
2503	45	22-Oct-2020	-	TERM
2504	45	22-Oct-2020	-	TERM
2505	45	22-Oct-2020	-	TERM
2506	45	22-Oct-2020	-	TERM
2507	45	22-Oct-2020	-	TERM
2508	45	22-Oct-2020	-	TERM
2509	45	22-Oct-2020	-	TERM
2510	45	22-Oct-2020	-	TERM
2511	45	22-Oct-2020	-	TERM
2512	45	22-Oct-2020	-	TERM
2513	45	22-Oct-2020	-	TERM
2514	45	22-Oct-2020	-	TERM
2515	45	22-Oct-2020	-	TERM

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2516	45	22-Oct-2020	-	TERM
2517	45	22-Oct-2020	-	TERM
2518	45	22-Oct-2020	-	TERM
2519	45	22-Oct-2020	-	TERM
2520	45	22-Oct-2020	-	TERM
2701	74	20-Nov-2020	TE	-
2702	74	20-Nov-2020	TE	-
2703	74	20-Nov-2020	TE	-
2704	74	20-Nov-2020	TE	-
2705	74	20-Nov-2020	TE	-

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IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Male Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Path Removal Reason
1101	74	20-Nov-2020	REC
1102	74	20-Nov-2020	REC
1103	74	20-Nov-2020	REC
1104	74	20-Nov-2020	REC
1105	74	20-Nov-2020	REC
1106	74	20-Nov-2020	REC
1107	74	20-Nov-2020	REC
1108	74	20-Nov-2020	REC
1109	74	20-Nov-2020	REC
1110	74	20-Nov-2020	REC
1111	74	20-Nov-2020	REC
1112	74	20-Nov-2020	REC
1113	74	20-Nov-2020	REC
1114	74	20-Nov-2020	REC
1115	74	20-Nov-2020	REC

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Male Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Path Removal Reason
1116	74	20-Nov-2020	REC
1117	74	20-Nov-2020	REC
1118	74	20-Nov-2020	REC
1119	74	20-Nov-2020	REC
1120	74	20-Nov-2020	REC

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Male Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2101	74	20-Nov-2020	-	REC
2102	74	20-Nov-2020	-	REC
2103	74	20-Nov-2020	-	REC
2104	74	20-Nov-2020	-	REC
2105	74	20-Nov-2020	-	REC
2106	74	20-Nov-2020	-	REC
2107	74	20-Nov-2020	-	REC
2108	74	20-Nov-2020	-	REC
2109	74	20-Nov-2020	-	REC
2110	74	20-Nov-2020	-	REC
2111	74	20-Nov-2020	-	REC
2112	74	20-Nov-2020	-	REC
2113	74	20-Nov-2020	-	REC
2114	74	20-Nov-2020	-	REC
2115	74	20-Nov-2020	-	REC

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

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Sex: Male Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2116	74	20-Nov-2020	-	REC
2117	74	20-Nov-2020	-	REC
2118	74	20-Nov-2020	-	REC
2119	74	20-Nov-2020	-	REC
2120	74	20-Nov-2020	-	REC
2201	74	20-Nov-2020	TE	-
2202	74	20-Nov-2020	TE	-
2203	74	20-Nov-2020	TE	-
2204	74	20-Nov-2020	TE	-
2205	74	20-Nov-2020	TE	-

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Removal Reason	Path Removal Reason
1601	74	20-Nov-2020	-	REC
1602	74	20-Nov-2020	-	REC
1603	74	20-Nov-2020	-	REC
1604	74	20-Nov-2020	-	REC
1605	74	20-Nov-2020	-	REC
1606	74	20-Nov-2020	-	REC
1607	74	20-Nov-2020	-	REC
1608	74	20-Nov-2020	-	REC
1609	74	20-Nov-2020	-	REC
1610	74	20-Nov-2020	-	REC
1611	74	20-Nov-2020	-	REC
1612	74	20-Nov-2020	-	REC
1613	74	20-Nov-2020	-	REC
1614	74	20-Nov-2020	-	REC
1615	74	20-Nov-2020	-	REC

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

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Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 1	Day of Death	Removal Date	Removal Reason	Path Removal Reason
1616	74	20-Nov-2020	-	REC
1617	74	20-Nov-2020	-	REC
1618	39	16-Oct-2020	FD	FD
1619	74	20-Nov-2020	-	REC
1620	74	20-Nov-2020	-	REC

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2601	74	20-Nov-2020	-	REC
2602	74	20-Nov-2020	-	REC
2603	74	20-Nov-2020	-	REC
2604	74	20-Nov-2020	-	REC
2605	74	20-Nov-2020	-	REC
2606	74	20-Nov-2020	-	REC
2607	74	20-Nov-2020	-	REC
2608	74	20-Nov-2020	-	REC
2609	74	20-Nov-2020	-	REC
2610	74	20-Nov-2020	-	REC
2611	74	20-Nov-2020	-	REC
2612	74	20-Nov-2020	-	REC
2613	74	20-Nov-2020	-	REC
2614	74	20-Nov-2020	-	REC
2615	74	20-Nov-2020	-	REC

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 2

Individual mortality

513351

Sex: Female Day(s): - Relative to Start Date

70 ul Group 2	Day of Death	Removal Date	Removal Reason	Path Removal Reason
2616	74	20-Nov-2020	-	REC
2617	74	20-Nov-2020	-	REC
2618	74	20-Nov-2020	-	REC
2619	74	20-Nov-2020	-	REC
2620	74	20-Nov-2020	-	REC
2701	74	20-Nov-2020	TE	-
2702	74	20-Nov-2020	TE	-
2703	74	20-Nov-2020	TE	-
2704	74	20-Nov-2020	TE	-
2705	74	20-Nov-2020	TE	-

TE/TERM = Terminal Euthanasia FD = Found Dead UE/UNSC = Unscheduled Euthanasia
IE/INTM = Interim Euthanasia REC = Recovery Euthanasia

Appendix 3

Individual clinical observations

Explanation page

Abbreviation	Description	Abbreviation	Description
PR	Predose	IPD	Immediately post dose
0-1H	0-1 hour post-dose	1-2H	1-2 hours post-dose
2-3H	2-3 hours post-dose	3-4H	3-4 hours post-dose
4-6H	4-6 hours post-dose	7H	7 hours post-dose
8-16H	8-16 hours post-dose	DE	Detailed examination
CSO AM or CAM	Sign of ill health or reaction to treatment observed in the morning or observation at the start of the day on non-dosing days.		
CSO PM or CPM	Sign of ill health or reaction to treatment observed in the afternoon or observation at the end of the day on non-dosing days.		
Clin obs	Clinical observations		
.	No abnormality detected, animal not examined or animal deceased.		
*	Comment present		
w/	with		
PT	Permanent		
Unsc	Unscheduled observation		
Color Not Rec	Colour not recorded		
SIRT/Cage Side Observations	Signs of ill-health in relation to treatment (post dose observations) and cage side observations.		

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

Only animals with clinical observations on at least one occasion are presented in this appendix.

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Appendix 3

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1001	Fur, Erected	2[CAM] to 8[CAM],14[CAM],16[CAM] to 17[CAM],21[CAM],22[1-2H],22[3-4H] to 27[CAM]
1002	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 17[CAM],21[CAM] to 27[CAM],29[CAM] to 33[CAM],36[DE],40[CAM] to 44[CAM]
1003	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],21[CAM] to 22[PR],22[IPD] to 22[1-2H],22[3-4H] to 23[CAM],28[CAM] to 31[CAM],36[DE],40[CAM] to 45[CAM]
1004	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 19[CAM],22[DE],22[1-2H] to 23[CAM],29[CAM] to 31[CAM],36[DE],40[CAM] to 44[CAM]
	Eyeball, Opacity, Right	22[DE],29[DE],36[DE],43[DE]
1005	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 36[DE],40[CAM] to 45[CAM]
1006	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],21[CAM] to 32[CAM],40[CAM] to 42[CAM],43[0-1H] to 45[CAM]
1007	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],21[CAM] to 22[PR],22[IPD] to 27[CAM],30[CAM] to 32[CAM],43[0-1H] to 43[3-4H],45[CAM]
1008	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 31[CAM],36[DE],38[CAM] to 43[3-4H]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1009	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 18[CAM],22[DE],22[1-2H] to 22[2-3H],23[CAM],26[CAM] to 32[CAM],36[DE],38[CAM] to 43[IPD],43[3-4H] to 44[CAM]
1010	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 22[PR],22[IPD] to 22[1-2H],22[3-4H] to 31[CAM],33[CAM],41[CAM] to 42[CAM],43[2-3H],44[CAM]
1011	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 13[CAM],15[DE] to 22[IPD],22[2-3H],23[CAM] to 27[CAM],29[CAM] to 43[IPD],43[2-3H] to 44[CAM]
	Activity Increased	15[DE],22[DE]
1012	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 11[CAM],13[CAM] to 22[1-2H],22[3-4H] to 33[CAM],36[CAM] to 36[DE],41[CAM] to 45[CAM]
1013	Fur, Erected	4[CAM] to 8[CAM],9[CAM] to 11[CAM],13[CAM],16[CAM] to 20[CAM],22[DE],22[2-3H] to 43[IPD],44[CAM] to 45[CAM]
1014	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 17[CAM],21[CAM] to 31[CAM],36[DE],40[CAM] to 43[3-4H]
	Skin, Discolored, Pinna, Left, Pale	22[2-3H]
	Skin, Discolored, Pinna, Right, Pale	22[2-3H]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1015	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 33[CAM],35[CAM],36[DE],40[CAM] to 43[3-4H],45[CAM]
1016	Skin, Scab, Dorsal Thoracic	1[DE],8[DE],15[DE]
	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM],21[CAM] to 22[IPD],22[1-2H] to 23[CAM],26[CAM] to 33[CAM],36[DE],40[CAM] to 45[CAM]
1017	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 22[DE],22[1-2H] to 22[2-3H],23[CAM] to 27[CAM],29[CAM] to 32[CAM],34[CAM],36[DE],40[CAM] to 45[CAM]
	Skin, Discolored, Pinna, Left, Pale	22[2-3H]
	Skin, Discolored, Pinna, Right, Pale	22[2-3H]
1018	Fur, Erected	4[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 18[CAM],21[CAM] to 34[CAM],36[CAM] to 36[DE],38[CAM] to 43[2-3H],44[CAM] to 45[CAM]
1019	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],22[1-2H] to 22[3-4H],26[CAM] to 27[CAM],35[CAM] to 36[CAM],37[CAM] to 42[CAM],43[2-3H] to 44[CAM]
1020	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],13[CAM] to 15[CAM],16[CAM] to 17[CAM],22[PR] to 25[CAM],29[CAM] to 44[CAM]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1101	Fur, Erected	17[CAM] to 27[CAM],30[CAM] to 31[CAM],33[CAM],36[CAM],37[CAM],40[CAM],43[2-3H],44[CAM]
1102	Fur, Erected	2[CAM] to 3[CAM],9[CAM] to 13[CAM],16[CAM],18[CAM],21[CAM] to 22[DE],22[0-1H] to 22[2-3H],23[CAM] to 27[CAM],29[DE] to 31[CAM],34[CAM],36[DE],43[DE],43[0-1H] to 45[CAM]
1103	Fur, Erected	2[CAM] to 3[CAM],7[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 18[CAM],21[CAM] to 22[2-3H],23[CAM] to 45[CAM]
1104	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],17[CAM] to 18[CAM],21[CAM] to 23[CAM],26[CAM] to 30[CAM],33[CAM] to 34[CAM],36[DE],38[CAM] to 44[CAM]
1105	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 17[CAM],21[CAM] to 22[IPD],22[1-2H] to 22[2-3H],23[CAM] to 27[CAM],29[CAM] to 29[DE],31[CAM],33[CAM],36[CAM] to 37[CAM],43[PR] to 44[CAM]
1106	Fur, Erected	3[CAM] to 6[CPM],9[CAM] to 15[CAM],16[CAM] to 23[CAM],28[CAM] to 29[DE],31[CAM],34[CAM],36[DE],43[DE],43[2-3H] to 43[3-4H]
	Eyeball, Protruding, Left	15[DE]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1106	Eyeball, Protruding, Right	15[DE]
	Activity Increased	15[DE]
1107	Fur, Erected	3[CAM] to 8[CAM],16[CAM] to 17[CAM],22[PR] to 22[2-3H],23[CAM] to 27[CAM],31[CAM],41[CAM] to 42[CAM],44[CAM]
1108	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 31[CAM],33[CAM] to 35[CAM],36[DE],40[CAM] to 45[CAM]
1109	Fur, Erected	3[CAM] to 8[CAM],10[CAM] to 15[CAM],16[CAM],22[PR] to 30[CAM],36[DE],40[CAM],43[PR] to 43[1-2H],43[3-4H]
1110	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 18[CAM],22[PR] to 22[2-3H],23[CAM] to 31[CAM],33[CAM],36[DE],40[CAM],43[PR] to 43[3-4H]
	Repetitive Behavior, Severity Not Recorded	15[DE],22[DE],29[DE]
1111	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 23[CAM],28[CAM] to 32[CAM],35[CAM] to 37[CAM],40[CAM] to 43[IPD],44[CAM] to 45[CAM]
	Skin, Discolored, Pinna, Left, Pale	22[2-3H]
	Skin, Discolored, Pinna, Right, Pale	22[2-3H]
1112	Skin, Scab, Hindlimb, Left	1[DE]
	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 17[CAM],22[DE],22[0-1H] to 27[CAM],29[CAM] to 31[CAM],33[CAM] to 43[IPD],43[3-4H]
	Hunched Posture	15[DE]

Values=Clin Obs Range

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Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1112	Activity Increased	15[DE]
	Skin, Discolored, Pinna, Left, Pale	22[2-3H]
	Skin, Discolored, Pinna, Right, Pale	22[2-3H]
1113	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 31[CAM],33[CAM] to 37[CAM],40[CAM] to 44[CAM]
	Skin, Discolored, Pinna, Left, Pale	22[2-3H]
	Skin, Discolored, Pinna, Right, Pale	22[2-3H]
1114	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 40[CAM],43[PR] to 45[CAM]
1115	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 34[CAM],36[DE],43[DE],43[2-3H] to 43[3-4H]
1116	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],21[CAM],22[DE],22[0-1H] to 27[CAM],29[DE],31[CAM],36[DE],43[PR] to 45[CAM]
	Activity Increased	15[DE],22[DE],29[DE],36[DE],43[DE]
1117	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 18[CAM],21[CAM] to 27[CAM],31[CAM],33[CAM],43[PR] to 43[IPD]
1118	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 15[CAM],16[CAM] to 22[PR],22[IPD],22[2-3H] to 43[IPD],43[3-4H] to 44[CAM]
1119	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],18[CAM] to 22[PR],22[IPD] to 22[1-2H],22[3-4H] to 27[CAM],30[CAM] to 33[CAM],41[CAM] to 43[IPD],44[CAM]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1120	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 18[CAM],21[CAM] to 27[CAM],29[CAM] to 31[CAM],33[CAM],36[DE],41[CAM] to 43[IPD],43[2-3H] to 43[3-4H]

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2001	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],22[PR] to 27[CAM],30[CAM],32[CAM],44[CAM] to 45[CAM]
2002	Fur, Erected	3[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],22[1-2H] to 23[CAM],28[CAM] to 29[CAM],30[CAM] to 33[CAM],38[CAM] to 42[CAM],43[0-1H] to 43[2-3H],44[CAM] to 45[CAM]
2003	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 45[CAM]
2004	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],22[PR] to 37[CAM],43[DE],43[0-1H] to 45[CAM]
2005	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 18[CAM],21[CAM] to 22[2-3H],23[CAM] to 28[CAM],30[CAM] to 33[CAM],35[CAM] to 36[CAM],37[CAM] to 39[CAM],43[0-1H] to 45[CAM]
2006	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 28[CAM],31[CAM] to 36[CAM],37[CAM] to 42[CAM],43[0-1H] to 45[CAM]
2007	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 31[CAM],33[CAM],36[DE],43[DE],43[0-1H] to 45[CAM]
	Tail, Bent (PT)	8[DE],15[DE],22[DE],29[DE],36[DE],43[DE]
2008	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],17[CAM],22[PR] to 31[CAM],33[CAM],38[CAM] to 42[CAM],43[0-1H] to 43[1-2H],43[3-4H] to 45[CAM]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2009	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 17[CAM],21[CAM] to 35[CAM],40[CAM] to 42[CAM],43[0-1H] to 45[CAM]
2010	Fur, Thin Cover, Dorsal Cervical	1[DE],8[DE]
	Skin, Scab, Dorsal Cervical	1[DE]
	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 18[CAM],21[CAM] to 33[CAM],41[CAM] to 45[CAM]
2011	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 31[CAM],34[CAM] to 35[CAM],38[CAM] to 43[0-1H],43[2-3H] to 45[CAM]
2012	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 32[CAM],34[CAM] to 45[CAM]
2013	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 17[CAM],21[CAM] to 37[CAM],41[CAM] to 45[CAM]
	Eyeball, Protruding, Left	15[DE],22[DE],29[DE],36[DE],43[DE]
	Eyeball, Protruding, Right	15[DE],22[DE],29[DE],36[DE],43[DE]
	Activity Increased	15[DE],22[DE],29[DE],36[DE],43[DE]
2014	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 33[CAM],38[CAM] to 39[CAM],41[CAM] to 42[CAM],43[0-1H] to 43[3-4H],45[CAM]
2015	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 33[CAM],35[CAM],38[CAM] to 43[IPD],43[3-4H] to 45[CAM]
2016	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],16[CAM] to 17[CAM],21[CAM],22[DE],22[0-1H] to 22[2-3H],23[CAM] to 27[CAM],30[CAM] to 31[CAM],33[CAM],40[CAM] to 42[CAM],43[0-1H] to 43[2-3H],44[CAM] to 45[CAM]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2017	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 13[CAM],15[DE] to 17[CAM],21[CAM],22[DE],22[0-1H] to 22[2-3H],23[CAM] to 32[CAM],40[CAM] to 42[CAM],43[1-2H] to 45[CAM]
2018	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 37[CAM],40[CAM] to 45[CAM]
2019	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 29[DE],31[CAM] to 45[CAM]
2020	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 29[DE],31[CAM] to 35[CAM],38[CAM] to 42[CAM],43[0-1H] to 43[3-4H],45[CAM]
2101	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 13[CAM],16[CAM] to 21[CAM],22[DE],22[1-2H] to 28[CAM],31[CAM] to 33[CAM],40[CAM] to 42[CAM],43[2-3H],44[CAM] to 45[CAM]
2102	Fur, Erected	2[CAM] to 6[CPM],9[CAM] to 22[3-4H],26[CAM] to 33[CAM],40[CAM] to 42[CAM],43[0-1H] to 45[CAM]
2103	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 20[CAM],22[PR] to 33[CAM],40[CAM] to 42[CAM],43[1-2H] to 45[CAM]
2104	Skin, Scab, Dorsal Cervical Fur, Erected	1[DE],8[DE] 2[CAM] to 8[CAM],9[CAM] to 17[CAM],22[DE],22[0-1H] to 33[CAM],43[0-1H] to 44[CAM]
2105	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 15[CAM],16[CAM] to 17[CAM],22[0-1H] to 22[2-3H],23[CAM] to 30[CAM],43[3-4H]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2106	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 33[CAM],40[CAM] to 43[3-4H]
	Hunched Posture	15[DE]
2107	Fur, Erected	2[CAM] to 6[CPM],14[CAM] to 21[CAM],22[DE],22[0-1H] to 28[CAM],29[DE],35[CAM] to 36[DE],40[CAM] to 45[CAM]
2108	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],21[CAM] to 22[PR],22[IPD] to 45[CAM]
2109	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 20[CAM],22[DE],22[0-1H] to 33[CAM],41[CAM] to 45[CAM]
2110	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 20[CAM],22[0-1H] to 31[CAM],33[CAM],43[3-4H] to 45[CAM]
2111	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 15[CAM],16[CAM] to 22[PR],22[IPD] to 22[2-3H],23[CAM] to 29[CAM],30[CAM] to 33[CAM],43[PR] to 43[IPD],44[CAM] to 45[CAM]
2112	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 22[PR],22[IPD] to 22[2-3H],23[CAM] to 45[CAM]
	Repetitive Behavior, Severity Not Recorded	15[DE],22[DE],29[DE],36[DE],43[DE]
	Activity Increased	15[DE],22[DE],29[DE],36[DE],43[DE]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2113	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 11[CAM],14[CAM] to 15[CAM],16[CAM] to 18[CAM],22[PR] to 23[CAM],26[CAM] to 27[CAM],31[CAM],40[CAM] to 42[CAM],43[2-3H] to 43[3-4H],45[CAM]
2114	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 31[CAM],33[CAM] to 34[CAM],40[CAM] to 45[CAM]
2115	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 33[CAM],43[PR] to 43[0-1H],43[2-3H] to 45[CAM]
2116	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 33[CAM],38[CAM] to 42[CAM],44[CAM] to 45[CAM]
	Hunched Posture	15[DE]
2117	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],22[DE],22[0-1H] to 23[CAM],26[CAM] to 43[IPD],43[1-2H] to 45[CAM]
2118	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 13[CAM],15[DE],17[CAM],22[PR] to 27[CAM],29[CAM] to 29[DE],43[2-3H] to 45[CAM]
	Skin, Scab, Dorsal Thoracic	8[DE]
2119	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 37[CAM],40[CAM] to 43[IPD],43[2-3H] to 45[CAM]
2120	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 17[CAM],22[PR],22[IPD] to 29[CAM],31[CAM] to 35[CAM],40[CAM] to 42[CAM],43[0-1H] to 43[2-3H],45[CAM]
	Activity Increased	15[DE]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 1 Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
1507	Fur, Thin Cover, Cranium	36[DE],43[DE]
1509	Repetitive Behavior, Severity Not Recorded	15[DE],22[DE],29[DE],36[DE],43[DE]
	Activity Increased	15[DE],22[DE],29[DE],36[DE],43[DE]
	Fur, Thin Cover, Dorsal Cervical	36[DE],43[DE]
	Fur, Thin Cover, Dorsal Thoracic	36[DE],43[DE]
1512	Fur, Ungroomed	36[DE]
1514	Whiskers Missing	36[DE],43[DE]
	Fur, Thin Cover, Muzzle	36[DE],43[DE]
1515	Whiskers Missing	43[DE]
1517	Repetitive Behavior, Severity Not Recorded	15[DE],22[DE],29[DE]
	Activity Increased	15[DE]
1518	Activity Increased	15[DE]
1613	Activity Increased	15[DE]

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2501	Fur, Thin Cover, Dorsal Cervical	1[DE],8[DE],15[DE],22[DE]
	Fur, Erected	2[CAM]
2502	Fur, Erected	2[CAM]
	Skin, Scab, Dorsal Cervical	43[DE]
2503	Fur, Erected	2[CAM]
2504	Fur, Erected	2[CAM] to 8[CAM]
2505	Fur, Erected	2[CAM] to 8[CAM]
2506	Fur, Erected	2[CAM] to 8[CAM]
2507	Fur, Erected	2[CAM] to 3[CAM]
2508	Fur, Erected	2[CAM] to 3[CAM]
2509	Fur, Erected	2[CAM] to 3[CAM]
	Fur, Thin Cover, Dorsal Cervical	8[DE],15[DE],22[DE],29[DE],36[DE],43[DE]
2510	Fur, Erected	2[CAM] to 3[CAM]
	Activity Increased	15[DE]
2513	Fur, Erected	2[CAM] to 3[CAM]
2514	Fur, Erected	2[CAM] to 3[CAM]
2515	Fur, Erected	2[CAM] to 3[CAM]
2516	Fur, Thin Cover, Dorsal Cervical	1[DE],8[DE],15[DE]
	Fur, Erected	2[CAM] to 3[CAM]
2517	Fur, Erected	2[CAM] to 3[CAM]
2518	Fur, Erected	2[CAM] to 3[CAM]
2519	Fur, Erected	2[CAM] to 3[CAM]
2520	Fur, Erected	2[CAM] to 3[CAM]
2601	Fur, Erected	2[CAM] to 8[CAM]
2602	Fur, Erected	2[CAM] to 3[CAM]
2603	Fur, Erected	2[CAM] to 3[CAM]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: pretreatment and dosing period

513351

70 ul Group 2 Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 45 (Start Date)
2604	Fur, Erected Fur, Thin Cover, Dorsal Cervical	2[CAM] to 3[CAM],7[CAM] to 8[CAM] 8[DE],15[DE],22[DE],29[DE],36[DE]
2605	Fur, Erected	2[CAM] to 3[CAM],7[CAM] to 8[CAM]
2606	Fur, Erected	2[CAM] to 3[CAM]
2607	Fur, Erected	2[CAM] to 3[CAM]
2608	Fur, Erected	2[CAM] to 3[CAM]
2609	Fur, Erected	2[CAM] to 3[CAM],24[CAM] to 25[CAM]
2611	Fur, Erected	2[CAM] to 3[CAM]
2613	Fur, Erected	2[CAM] to 3[CAM]
2614	Fur, Erected	2[CAM] to 3[CAM]
2615	Fur, Erected	2[CAM] to 3[CAM],13[CAM] to 15[CAM]
2616	Fur, Erected	2[CAM] to 8[CAM]
2617	Fur, Erected	2[CAM] to 8[CAM]
2618	Fur, Erected	2[CAM] to 3[CAM]
2619	Fur, Erected	2[CAM] to 3[CAM]
2620	Fur, Erected	2[CAM] to 3[CAM]

Appendix 3

Individual clinical observations: recovery period

513351

70 ul Group 1 Sex: Male	Observation Type: All Types	From Day 45 (Start Date) to 74 (Start Date)
1102	Fur, Erected	45[CAM] to 52[CAM]
1103	Fur, Erected	45[CAM] to 56[CAM]
1104	Fur, Erected	48[CAM] to 50[DE],53[CAM] to 55[CAM]
1105	Fur, Erected	50[DE]
1106	Fur, Erected	50[DE]
1107	Fur, Erected	53[CAM]
1108	Fur, Erected	45[CAM] to 50[DE],53[CAM]
1109	Fur, Erected	50[DE],57[DE]
1110	Fur, Erected	50[DE],54[CAM] to 55[CAM],57[DE]
1111	Fur, Erected	45[CAM] to 52[CAM],54[CAM] to 64[DE],71[DE]
1112	Fur, Erected	50[DE]
	Activity Increased	50[DE],57[DE],64[DE],71[DE]
1113	Fur, Erected	50[DE],57[DE]
1114	Fur, Erected	45[CAM] to 54[CAM]
1115	Fur, Erected	50[DE],53[CAM] to 54[CAM],57[DE],64[DE],71[DE]
1116	Fur, Erected	45[CAM] to 53[CAM]
	Activity Increased	50[DE],57[DE],64[DE],71[DE]
1117	Fur, Erected	50[DE]
1118	Fur, Erected	50[DE],57[DE]
1119	Fur, Erected	50[DE],57[DE],64[DE],71[DE]
1120	Fur, Erected	50[DE],53[CAM] to 54[CAM],57[DE],64[DE],71[DE]

Appendix 3

Individual clinical observations: recovery period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day 45 (Start Date) to 74 (Start Date)
2101	Fur, Erected	45[CAM] to 50[CAM],55[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 71[CAM],72[CAM] to 74[CAM]
2102	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 54[CAM]
	Activity Increased	57[DE],64[DE],71[DE]
2103	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 69[CAM]
	Fur, Ungroomed	50[DE],57[DE],64[DE],71[DE]
	Activity Increased	50[DE],57[DE]
2104	Activity Increased	71[DE]
2106	Fur, Erected	50[DE],57[DE]
2107	Fur, Erected	45[CAM] to 57[DE],64[DE],71[DE]
2108	Fur, Erected	45[CAM] to 46[CAM],50[DE],57[DE],64[DE],71[DE]
2109	Fur, Erected	45[CAM] to 53[CAM]
2110	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 71[CAM],72[CAM]
2111	Fur, Erected	45[CAM] to 64[CAM]
2112	Fur, Erected	45[CAM] to 54[CAM],57[DE],64[DE],71[DE]
	Repetitive Behavior, Severity Not Recorded	50[DE],57[DE]
	Activity Increased	50[DE],57[DE],64[DE],71[DE]
2113	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 53[CAM]
2114	Fur, Erected	45[CAM] to 55[CAM],73[CAM] to 74[CAM]
2115	Fur, Erected	45[CAM] to 53[CAM]
2116	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 69[CAM]
2117	Fur, Erected	45[CAM] to 55[CAM],57[DE] to 69[CAM],71[DE]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: recovery period

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day 45 (Start Date) to 74 (Start Date)
2118	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 69[CAM]
2119	Fur, Erected	45[CAM] to 64[CAM],65[CAM] to 71[CAM],72[CAM] to 74[CAM]
2120	Fur, Erected	45[CAM] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM]

Appendix 3

Individual clinical observations: recovery period

513351

70 ul Group 2 Sex: Female	Observation Type: All Types	From Day 45 (Start Date) to 74 (Start Date)
2601	Fur, Thin Cover, Dorsal Thoracic	64[DE]
2602	Hunched Posture	54[CAM]
	Fur, Erected	54[CAM]
	Fur, Staining, Eyelid, Left, Color Not Recorded	54[CAM]
	Fur, Staining, Eyelid, Right, Color Not Recorded	54[CAM]
	Eye Closed, Left, Partly	54[CAM]
	Eye Closed, Right, Partly	54[CAM]
2608	Fur, Thin Cover, Dorsal Thoracic	64[DE],71[DE]

Appendix 3

Individual clinical observations: immunogenicity animals

513351

70 ul Group 2 Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 74 (Start Date)
2201	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM],22[0-1H] to 29[CAM],31[CAM],33[CAM],44[CAM] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 69[CAM]
	Hunched Posture	54[CAM] to 57[CAM]
2202	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 32[CAM],40[CAM] to 42[CAM],43[2-3H] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM],65[CAM] to 69[CAM]
2203	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 30[CAM],33[CAM] to 37[CAM],41[CAM] to 43[IPD],43[1-2H] to 54[CAM],57[DE] to 69[CAM],71[DE]
	Activity Increased	64[DE],71[DE]
2204	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 17[CAM],21[CAM] to 35[CAM],41[CAM] to 43[IPD],43[1-2H] to 54[CAM],57[DE],64[DE],71[DE]
	Activity Increased	57[DE],64[DE],71[DE]
2205	Fur, Erected	2[CAM] to 8[CAM],9[CAM] to 15[CAM],16[CAM] to 22[Pre],22[IPD] to 22[2-3H],23[CAM] to 29[CAM],30[CAM] to 35[CAM],40[CAM] to 42[CAM],43[2-3H] to 50[CAM],51[CAM] to 57[CAM],58[CAM] to 64[CAM]

Values=Clin Obs Range

Appendix 3

Individual clinical observations: immunogenicity animals

513351

70 ul Group 2 Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 74 (Start Date)
2701 2704 2705	Fur, Thin Cover, Cranium Fur, Erected Fur, Erected Fur, Erected	1[DE],8[DE],15[DE],22[DE] 2[CAM] to 3[CAM] 2[CAM] to 3[CAM] 2[CAM] to 3[CAM]

Appendix 4

Individual body temperatures

Explanation page

Abbreviation	Description	Abbreviation	Description
DE	Pre-study recording	CAM	24 hours post Day 1 dose
4H	4 hours post-dose on Day 22	RC	Result comment

The Day 1 body temperatures were collected as 4 hours post-dose.

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 4

Individual body temperatures

513351
Sex: Male Body Temperature (oC)

70 ul Group 1	Day(s) Relative to Start Date					
	-7 (DE)	1	2 (CAM)	21	22 (4H)	23
1001	38.3	36.1	38.1	37.3	36.2	37.0
1002	37.2	36.6	37.6	36.2	36.2	38.1
1003	37.0	36.1	36.6	37.4	38.7	39.2
1004	36.7	37.0	39.1 [a]	38.4	37.0	38.4
1005	36.8	37.3	38.1	37.5	37.2	39.0
1006	36.7	37.3	37.7	36.3	36.5	38.9
1007	36.1	37.3	37.6	36.4	36.5	38.0
1008	37.2	37.5	37.7	37.0	37.6	38.6
1009	37.4	37.6	38.0	36.9	37.0	38.6
1010	37.8	38.6	38.7	35.9 [a]	36.9	39.4
Mean	37.12	37.14	37.92	36.93	36.98	38.52
SD	0.62	0.75	0.68	0.75	0.75	0.70
N	10	10	10	10	10	10

[a] [RC:Value Confirmed]

Appendix 4

Individual body temperatures

513351
Sex: Male Body Temperature (oC)

70 ul Group 2	Day(s) Relative to Start Date					
	-7 (DE)	1	2 (CAM)	21	22 (4H)	23
2001	36.1	36.4	36.5	36.0	36.2	36.4
2002	36.7	36.5	37.7	36.8	36.4	38.6
2003	36.1	37.8	36.6	36.6	38.1	39.4
2004	36.4	36.7	37.7	38.3	38.1	39.0
2005	36.3	37.0	37.8	36.7	38.7	38.8
2006	37.0	37.7	38.3	37.1	38.7	39.3
2007	37.9	38.7	38.7	37.9	38.6	39.1
2008	37.2	38.4	39.0 [a]	37.3	38.9	38.6
2009	36.7	38.2	39.8 [a]	37.7	39.3	38.8
2010	36.9	38.7	39.5 [a]	37.9	39.5	39.7
Mean	36.73	37.61	38.16	37.23	38.25	38.77
SD	0.56	0.90	1.12	0.72	1.12	0.91
N	10	10	10	10	10	10
%Diff	-1.05	1.27	0.63	0.81	3.43	0.65

[a] [RC:Value Confirmed]

Appendix 4

Individual body temperatures

513351
Sex: Female Body Temperature (oC)

70 ul Group 1	Day(s) Relative to Start Date					
	-7 (DE)	1	2 (CAM)	21	22 (4H)	23
1501	37.6	37.9	38.7	36.7	36.4	38.8
1502	37.4	36.9	38.3	37.7	37.2	37.7
1503	37.2	37.0	38.2	37.1	36.8	36.9
1504	36.9	37.6	38.1	37.8	37.2	37.2
1505	37.2	37.6	37.6	37.4	37.2	36.9
1506	37.4	38.0	37.7	37.5	37.7	38.0
1507	37.5	37.7	38.0	37.6	36.8	37.4
1508	37.2	37.1	37.8	37.6	36.8	38.2
1509	38.0	38.1	39.1	37.6	36.5	38.7
1510	37.3	37.5	38.1	37.5	37.4	38.0
Mean	37.37	37.54	38.16	37.45	37.00	37.78
SD	0.29	0.42	0.46	0.32	0.41	0.68
N	10	10	10	10	10	10

Appendix 4

Individual body temperatures

513351
Sex: Female Body Temperature (oC)

70 ul Group 2	Day(s) Relative to Start Date					
	-7 (DE)	1	2 (CAM)	21	22 (4H)	23
2501	37.4	37.3	37.5	37.6	37.6	38.3
2502	36.6	37.9	37.6	36.2	37.2	38.6
2503	36.4	37.9	37.9	37.2	37.1	38.1
2504	36.6	37.6	37.3	37.5	37.0	37.2
2505	37.1	38.7	38.0	37.1	37.6	38.3
2506	37.7	38.2	37.0	37.9	37.7	37.6
2507	37.4	38.1	38.1	37.3	36.9	38.6
2508	38.1	38.0	37.2	37.1	37.2	38.5
2509	37.2	37.4	37.8	37.3	37.4	38.1
2510	37.4	37.4	38.2	37.3	37.5	38.9
Mean	37.19	37.85	37.66	37.25	37.32	38.22
SD	0.53	0.44	0.41	0.44	0.28	0.51
N	10	10	10	10	10	10
%Diff	-0.48	0.83	-1.31	-0.53	0.86	1.16

Appendix 5

Individual body weights (g)

Explanation page

Abbreviation	Description
AVS	Aberrant value suppressed/excluded
RC	Result comment
X	Excluded from mean
-	Animal deceased or collection not scheduled to be performed unless otherwise listed below

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

The bodyweight recorded on Day 39 for Animal 1618 is a terminal body weight and has been excluded from statistical analysis.

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
1001	31.2	33.1	32.2	32.6	32.3	33.4	33.8
1002	35.6	38.4	37.6	38.0	37.7	38.7	39.1
1003	32.5	33.8	33.7	34.7	34.2	34.9	35.2
1004	32.1	33.7	33.7	33.6	33.8	34.0	33.6
1005	32.7	33.8	33.9	34.8	34.5	34.1	35.5
1006	33.0	34.3	34.1	33.9	34.2	34.9	35.0
1007	34.6	35.1	34.5	34.6	34.4	34.9	34.8
1008	32.9	33.7	34.0	34.4	33.7	33.7	33.9
1009	31.9	33.0	32.9	32.9	32.9	33.4	34.0
1010	32.8	34.1	33.6	34.8	34.9	35.4	35.3
1011	31.2	33.0	33.3	34.1	34.3	35.0	36.2
1012	31.4	33.4	32.9	33.3	33.8	33.9	35.9
1013	31.0	32.0	31.8	32.1	32.2	33.0	33.5
1014	34.3	37.0	37.7	37.7	37.6	38.3	38.6
1015	31.3	33.4	33.5	33.5	33.6	33.4	34.4
1016	33.8	35.0	34.5	35.1	34.7	35.4	35.8
1017	35.2	35.5	35.4	35.2	35.2	35.8	36.1
1018	31.5	32.1	32.3	32.4	32.5	32.3	32.4
1019	36.7	38.0	37.8	38.5	38.3	38.2	39.0

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
1001	33.7	34.7	35.7	35.0	35.1	35.4	35.1
1002	39.2	40.0	40.3	40.2	40.5	40.5	40.9
1003	36.2	36.5	38.6	37.7	37.9	37.9	36.7
1004	35.5	33.5 [a]	34.4	33.6	33.9	34.2	36.0
1005	35.6	36.0	39.0	38.0	39.0	38.7	36.9 [a]
1006	35.4	35.9	36.8	36.3	36.5	37.1	36.2
1007	35.3	36.0	36.3	36.0	35.8	35.6	34.7
1008	34.5	35.5	36.7	36.4	37.0	36.4	36.3
1009	34.8	36.1	35.6	35.7	36.1	36.4	35.8
1010	35.6	36.1	36.7	37.5	37.3	37.5	37.7
1011	35.4	37.2	36.4	36.4	36.7	36.4	37.9
1012	35.7	37.5	36.9	37.4	37.9	38.0	37.4
1013	33.4	34.5	35.3	35.6	36.5	36.3	35.1
1014	38.5	39.8	40.5	41.2	41.6	41.9	41.3
1015	34.3	35.3	35.9	36.3	36.7	36.7	35.7
1016	35.7	35.6	35.5	35.8	36.2	36.5	36.4
1017	36.9	37.6	38.1	39.2	39.1	38.3	38.7
1018	33.0	33.6	33.7	34.7	34.8	34.8	33.5
1019	39.7	40.8	41.2	40.8	41.0	41.9	40.8

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date					
	32	36	39	43	44	45
1001	36.0	35.9	36.6	36.0	36.0	36.7
1002	42.6	42.7	43.4	42.7	43.0	42.5
1003	36.7	37.5	37.7	37.1	38.0	37.1
1004	35.7	37.1	36.7	36.8	36.8	36.7
1005	39.0	38.4	38.7	37.9	38.2	37.9
1006	37.6	38.0	38.5	37.9	38.6	39.0
1007	35.5	35.4	36.3	36.2	36.3	36.7
1008	35.9	36.4	36.3	36.1	37.4	37.5
1009	36.3	36.5	37.0	37.3	37.1	37.6
1010	38.2	37.5	37.7	38.6	38.9	38.8
1011	37.3	39.0	38.3	37.3	37.9	38.3
1012	37.6	38.2	38.3	39.0	39.9	39.5
1013	36.9	37.1	37.7	37.1	37.7	38.4
1014	41.5	41.4	42.1	41.6	42.5	42.3
1015	36.4	36.0	37.5	36.0	36.7	36.9
1016	36.6	36.5	37.6	36.8	36.6	37.0
1017	39.0	39.2	40.7	40.4	40.2	40.6
1018	34.5	34.6	34.8	34.8	35.0	35.4
1019	42.1	40.8	42.1	41.9	42.8	42.4

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
1020	32.0	33.9	33.3	34.9	34.3	33.9	34.7
1101	30.6	31.0	30.9	31.5	31.4	31.8	32.2
1102	33.8	34.3	33.4	33.6	33.8	33.3	33.3
1103	33.4	34.4	33.7	34.3	34.5	33.9	34.7
1104	33.6	35.8	35.2	35.4	35.3	35.2	35.8
1105	30.8	32.9	32.8	32.7	32.6	33.7	33.1
1106	34.5	36.1	36.4	36.9	37.1	37.6	38.4
1107	32.2	35.1	34.5	35.9	35.7	35.3	36.2
1108	30.2	34.5	34.6	35.6	35.2	35.6	35.7
1109	32.9	35.0	33.8	34.4	34.7	36.0	36.1
1110	36.1	38.1	37.9	38.8	39.4	38.6	39.9
1111	33.8	34.7	34.5	35.2	34.9	35.0	35.9
1112	38.0	40.4	40.5	42.2	41.9	42.8	43.4
1113	36.3	38.4	38.1	39.7	39.7	40.3	41.3
1114	34.5	35.7	34.7	34.8	34.7	35.1	35.5
1115	34.5	36.4	35.7	36.0	36.2	36.4	36.9
1116	33.9	36.0	35.9	35.8	36.8	36.9	37.3
1117	33.9	34.3	34.2	34.8	34.9	35.4	35.6
1118	34.9	35.2	36.0	38.0	37.0	36.6	37.5

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
1020	35.0	36.3	36.8	37.5	37.8	38.3	37.6
1101	32.1	33.1	34.5	34.4	34.4	34.2	34.8
1102	33.1	33.9	34.2	34.5	35.1	35.0	35.3
1103	35.0	35.5	36.4	36.3	36.0	36.6	36.1
1104	36.0	37.2	38.4	37.8	36.8	38.5	38.4
1105	33.2	34.5	35.3	34.8	34.9	34.6	34.7
1106	38.5	38.9	39.7	40.0	40.3	40.2	40.5
1107	36.8	37.3	37.6	38.8	38.5	38.8	38.3
1108	35.5	37.2	38.1	38.6	38.8	38.8	39.1
1109	35.7	35.7	36.2	36.4	36.5	36.3	37.0
1110	40.4	42.5	40.9	42.6	42.1	42.8	42.7
1111	35.3	36.7	36.7	36.8	37.1	38.3	37.4
1112	43.6	45.3	44.8	45.7	45.7	46.7	45.2
1113	41.1	43.4	42.0	42.8	43.1	43.3	44.0
1114	34.1	35.5	36.7	36.7	36.8	37.5	37.1
1115	36.5	38.1	38.7	38.6	39.1	39.8	39.2
1116	37.3	39.0	38.8	39.5	38.8	40.0	39.5
1117	35.6	36.1	36.9	37.6	38.1	38.1	38.5
1118	38.7	38.8	38.9	38.7	39.0	40.2	39.7

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date					
	32	36	39	43	44	45
1020	38.6	38.1	39.2	38.1	38.9	38.8
1101	35.9	36.5	36.0	37.6	37.9	38.1
1102	35.6	35.7	35.2	36.2	36.7	36.9
1103	36.9	37.3	37.3	36.8	37.1	38.5
1104	38.5	39.9	39.3	39.4	38.8	39.5
1105	35.2	35.6	35.7	36.2	36.0	36.4
1106	41.2	39.8	40.9	39.6	40.0	41.3
1107	38.3	37.7	39.4	38.0	38.9	38.8
1108	39.9	39.5	39.5	38.1	40.0	40.4
1109	37.6	37.6	38.5	38.1	38.7	38.9
1110	42.5	42.7	42.5	42.1	43.0	43.6
1111	36.8	37.3	38.1	37.3	38.0	38.6
1112	46.1	46.2	47.6	46.3	48.9	49.1
1113	43.8	44.0	43.7	43.0	43.6	44.5
1114	37.6	37.7	37.5	38.2	38.9	38.8
1115	40.2	40.6	40.9	41.5	41.9	42.6
1116	38.4	38.3	39.3	38.4	40.0	41.5
1117	38.2	38.4	39.9	39.2	40.2	40.4
1118	38.8	39.9	39.9	38.7	39.4	40.2

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
1119	33.5	36.0	36.2	35.9	36.3	36.5	37.8
1120	33.1	35.3	35.9	36.5	36.7	37.4	37.4
Mean	33.31	34.90	34.69	35.23	35.20	35.50	36.02
SD	1.80	1.94	1.98	2.20	2.19	2.23	2.36
N	40	40	40	40	40	40	40

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
1119	37.5	37.2	38.2	38.9	39.0	39.0	38.9
1120	37.6	37.7	38.7	39.1	39.5	39.4	39.5
Mean	36.18	37.05	37.55	37.75	37.93	38.17	37.92
SD	2.38	2.64	2.32	2.54	2.49	2.67	2.60
N	40	40	40	40	40	40	40

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date					
	32	36	39	43	44	45
1119	39.5	39.3	40.6	40.4	41.2	42.4
1120	41.2	40.6	42.1	40.4	41.4	42.2
Mean	38.41	38.52	39.03	38.63	39.23	39.57
SD	2.59	2.47	2.63	2.39	2.68	2.72
N	40	40	40	40	40	40

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2001	33.5	34.7	34.5	34.2	34.3	35.3	34.7
2002	30.6	33.4	32.7	32.6	33.3	34.0	34.5
2003	33.0	35.5	35.2	34.7	34.8	35.9	35.9
2004	34.0	35.0	35.4	35.4	35.4	35.1	36.2
2005	33.8	34.1	32.6 [a]	33.1	33.0	33.9	33.2
2006	33.4	36.5	35.1	36.3	35.7	37.2	37.3
2007	32.7	34.2	33.6	34.4	34.4	35.0	36.0
2008	33.4	35.6	35.4	36.0	35.4	36.8	37.3
2009	31.9	33.3	33.8	34.4	34.0	34.4	34.7
2010	34.3	36.6	35.4	35.8	36.0	36.5	36.5
2011	34.9	37.1	36.1	37.3	37.1	37.3	37.7
2012	34.5	38.1	37.5	37.4	37.0	37.5	37.7
2013	34.3	36.5	36.1	36.8	36.5	36.6	36.9
2014	34.4	35.4	34.8	36.1	35.5	35.4	36.3
2015	37.0	40.0	39.5	39.9	39.4	40.4	40.2
2016	30.6	32.9	32.4	32.6	32.5	32.6	32.4
2017	31.4	32.8	32.0	33.5	32.9	33.7	33.5
2018	32.2	34.0	33.6	34.5	33.9	34.6	35.1
2019	33.4	36.1	35.1	36.3	36.2	36.5	36.7

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2001	34.7	35.2	35.8	35.7	36.1	36.4	35.7
2002	34.2	36.1	37.5	36.8	36.6	37.6	37.0
2003	36.4	37.1	38.8	38.3	37.8	38.6	37.1
2004	36.4	36.3	35.1	36.2	36.1	36.6	37.4
2005	33.3	34.3	34.4	34.3	33.9	34.5	33.8
2006	37.5	39.0	39.8	39.4	39.4	40.4	38.8
2007	36.4	37.5	36.8	36.5	36.8	38.0	37.3
2008	38.1	38.1	40.0	39.1	39.0	39.3	39.7
2009	35.5	36.1	35.5	35.9	36.0	37.3	37.4
2010	37.6	38.4	39.4	39.7	39.6	39.8	40.2
2011	38.1	38.8	38.6	39.4	39.1	40.6	39.5
2012	38.4	39.4	38.9	39.3	40.2	40.9	39.6
2013	36.8	38.3	38.2	39.4	38.7	39.5	37.8 [a]
2014	35.6	36.5	36.9	38.1	38.1	37.8	37.7
2015	40.6	41.6	43.6	42.9	43.3	42.8	42.1
2016	32.8	33.6	33.9	34.9	35.0	34.9	34.2
2017	34.7	35.2	35.4	35.9	37.2	36.7	36.3
2018	35.6	36.0	36.0	36.4	37.1	37.9	37.3
2019	36.7	37.9	38.4	39.4	39.8	38.8	38.0

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date					
	32	36	39	43	44	45
2001	36.4	36.5	37.2	37.9	37.8	37.4
2002	37.4	38.1	38.3	39.2	38.6	38.1
2003	38.8	38.4	39.0	38.8	39.4	39.6
2004	36.3	35.6	36.0	35.5	36.1	36.9
2005	35.1	35.2	36.3	35.8	36.5	37.0
2006	40.4	40.0	40.9	41.5	41.5	41.9
2007	37.4	36.8	38.6	37.7	37.8	37.9
2008	39.4	40.7	40.0	40.4	41.4	41.1
2009	37.4	36.6	37.7	37.7	38.0	38.3
2010	40.6	40.8	41.5	41.2	41.9	41.8
2011	39.8	39.8	40.6	40.3	40.8	40.5
2012	40.3	40.1	42.3	41.4	42.4	42.5
2013	39.5	38.7	40.2	39.0	40.6	40.5
2014	37.6	39.3	38.9	39.0	39.8	39.3
2015	42.4	43.4	43.4	43.7	44.6	45.2
2016	34.3	34.3	33.9	35.2	36.0	36.5
2017	37.6	37.4	37.1	36.6	37.1	37.1
2018	38.3	38.5	38.9	37.6	38.7	38.9
2019	38.6	39.4	40.3	40.5	41.3	41.5

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2020	34.1	36.9	37.1	38.6	37.8	38.0	38.6
2101	33.0	36.0	35.4	36.3	35.9	37.7	37.7
2102	31.7	33.4	33.9	34.5	34.4	34.2	34.6
2103	35.4	37.7	36.6	37.4	37.8	37.9	37.8
2104	32.4	34.7	35.2	35.7	35.7	34.5 [a]	34.9
2105	33.9	36.3	35.4	36.2	35.2	35.0	36.8
2106	33.1	35.6	34.7	36.3	36.0	35.7	35.8
2107	33.8	36.4	36.9	37.9	37.0	37.0	37.8
2108	34.3	36.7	36.8	37.8	37.3	36.9	37.5
2109	35.0	36.4	37.2	37.8	37.8	37.0	38.4
2110	33.4	34.6	33.6	34.3	34.2	34.1	33.9
2111	32.7	35.0	34.4	35.2	35.5	36.0	36.2
2112	35.6	37.3	34.7 [a]	35.9	36.3	37.7	37.3
2113	32.1	34.1	32.6	33.5	34.5	34.7	35.2
2114	32.1	33.3	32.4	33.6	33.0	33.5	33.4
2115	32.3	34.2	33.5	34.4	34.8	35.0	36.0
2116	30.7	32.1	30.9	32.5	32.7	32.8	34.0
2117	32.5	34.8	32.9 [a]	34.5	34.5	35.1	35.1
2118	34.3	36.1	35.5	36.3	36.4	36.9	37.3

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2020	40.5	40.1	40.2	40.8	41.4	41.3	40.8
2101	37.9	38.7	39.7	40.0	40.1	39.8	39.5
2102	34.4	35.4	36.3	36.9	37.3	37.1	37.1
2103	38.0	39.5	37.8 [a]	39.1	39.9	40.1	39.3
2104	35.8	35.6	35.8	36.2	37.7	38.0	38.5
2105	36.9	36.6	37.0	36.0	36.8	37.8	38.6
2106	36.6	37.1	37.1	37.4	38.0	38.6	37.8
2107	37.4	38.7	38.4	39.3	40.0	39.4	38.8
2108	38.4	39.4	40.1	40.5	40.9	41.3	41.0
2109	37.7	36.6	37.3	37.6	37.9	38.5	40.5
2110	35.1	35.7	36.4	36.5	36.4	36.7	36.3
2111	36.0	36.8	36.6	37.8	38.0	37.7	37.9
2112	37.6	39.2	39.2	39.6	40.3	40.2	39.6
2113	34.8	35.5	36.0	36.2	36.9	36.7	36.4
2114	34.2	35.6	35.5	36.0	36.1	35.2	36.2
2115	35.8	37.0	37.0	37.8	38.2	37.8	38.3
2116	33.4	35.7	36.2	36.4	36.6	36.7	36.2
2117	35.4	36.3	36.7	37.6	37.5	36.6	37.0
2118	37.7	38.6	39.2	39.2	39.6	39.1	38.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date					
	32	36	39	43	44	45
2020	42.4	42.1	43.1	42.3	43.6	42.9
2101	40.1	39.9	40.2	41.5	42.0	41.6
2102	37.5	36.5	37.1	37.4	38.2	38.5
2103	39.3	38.1	38.3	38.4	39.9	39.3
2104	38.0	38.1	38.9	38.7	39.3	39.0
2105	37.4	38.2	38.3	39.3	39.2	38.8
2106	38.1	37.8	38.3	38.1	37.9	37.8
2107	40.4	39.5	41.3	40.7	41.7	41.8
2108	41.8	40.5	40.7	40.4	41.4	41.3
2109	38.3 [a]	39.2	39.7	39.9	40.2	41.7
2110	36.9	36.0	37.2	35.2 [a]	37.2	37.1
2111	37.9	37.9	38.3	39.1	39.6	39.8
2112	40.2	40.3	40.8	39.9	41.1	41.0
2113	37.0	37.4	37.7	38.2	39.0	39.1
2114	36.2	35.9	35.4	35.9	35.9	36.4
2115	38.6	39.4	38.9	39.4	39.7	39.2
2116	37.5	37.7	37.3	36.7	38.4	38.9
2117	37.7	37.7	38.3	38.0	38.8	39.2
2118	39.8	40.5	41.0	41.5	42.4	41.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2119	31.4	33.5	32.9	34.3	34.2	34.7	34.9
2120	33.9	35.4	35.3	35.8	36.4	37.6	37.7
Mean	33.28	35.31	34.72	35.50	35.37	35.77	36.09
SD	1.42	1.65	1.77	1.73	1.61	1.66	1.71
N	40	40	40	40	40	40	40
%Diff	-0.09	1.17	0.08	0.78	0.48	0.75	0.20

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2119	35.2	36.2	36.9	36.8	36.8	36.7	35.7
2120	37.8	38.6	38.6	39.7	40.0	39.6	39.9
Mean	36.40	37.21	37.53	37.88	38.16	38.33	38.03
SD	1.79	1.74	1.92	1.86	1.90	1.86	1.81
N	40	40	40	40	40	40	40
%Diff	0.62	0.42	-0.07	0.34	0.61	0.42	0.30

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date					
	32	36	39	43	44	45
2119	36.3	36.2	36.1	36.5	38.1	37.7
2120	39.3	39.2	38.9	38.1	38.9	37.7
Mean	38.46	38.44	38.92	38.86	39.57	39.57
SD	1.84	1.93	2.07	2.06	2.10	2.05
N	40	40	40	40	40	40
%Diff	0.14	-0.21	-0.27	0.59	0.87	-0.01

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
1501	26.2	25.9	24.6 [a]	26.2	27.5	29.7	28.0 [a]
1502	24.1	24.5	25.0	25.9	25.3	26.8	28.9
1503	27.4	29.1	28.0	29.0	29.3	29.1	28.8
1504	26.3	29.6	29.7	30.4	31.0	30.1	29.3
1505	26.7	28.8	27.4 [a]	27.8	28.8	28.7	28.6
1506	23.4	23.9	24.0	24.0	24.3	24.6	24.4
1507	26.4	27.7	28.1	29.3	29.6	29.2	30.3
1508	24.4	25.8	26.2	26.3	26.4	26.8	27.6
1509	23.8	24.4	24.4	25.1	25.7	26.1	26.9
1510	24.0	26.2	26.7	27.4	27.8	26.7	28.2
1511	25.3	26.5	25.5	26.5	26.6	26.3	27.8
1512	23.8	23.9	23.2	24.0	24.0	23.9	24.1
1513	24.5	25.7	25.3	26.4	24.8 [a]	26.0	27.4
1514	22.7	25.4	23.9	24.2	24.8	25.5	25.4
1515	24.4	26.7	25.7	26.8	27.2	28.6	31.1
1516	22.7	24.6	24.4	25.6	25.4	27.2	25.8 [a]
1517	26.2	26.6	26.1	27.1	27.1	27.6	28.4
1518	25.7	26.0	25.4	26.6	27.0	27.5	26.6
1519	24.2	25.3	25.8	24.8	25.4	25.2	26.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
1501	28.2	29.8	29.1	28.8	29.1	30.1	29.7
1502	27.2 [a]	28.8	29.1	26.8 [a]	27.6	27.6	28.6
1503	28.7	28.5	28.9	29.1	29.6	29.9	30.4
1504	28.7	31.1	31.3	30.4	31.5	29.4 [a]	32.0
1505	28.4	30.1	30.4	31.1	31.5	32.2	33.0
1506	24.9	24.9	25.0	25.0	25.2	25.1	25.9
1507	31.0	33.7	30.9 [a]	31.9	32.3	32.9	33.9
1508	28.3	29.2	29.3	28.4	28.4	28.6	29.2
1509	27.1	26.9	26.7	27.0	27.5	27.6	28.2
1510	27.4	29.6	28.7	27.8	28.0	28.7	31.1
1511	28.8	29.5	29.4	30.4	28.8 [a]	29.2	29.8
1512	25.3	27.9	26.1 [a]	26.9	26.7	27.4	26.6
1513	29.3	29.0	31.6	32.2	32.2	31.4	31.5
1514	25.9	26.9	27.1	27.3	27.8	27.8	28.2
1515	32.5	29.5 [a]	30.6	32.4	32.2	30.4 [a]	33.5
1516	25.5	26.7	26.0	25.8	25.5	26.5	25.8
1517	29.0	28.3	30.3	28.1 [a]	29.1	28.7	30.9
1518	26.9	27.4	28.2	29.5	29.5	28.1 [a]	28.6
1519	27.8	26.7	27.5	28.7	30.2	30.1	29.8

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date					
	32	36	39	43	44	45
1501	29.8	29.4	29.9	31.7	33.6	33.8
1502	28.4	30.7	30.0	29.2	31.4	31.0
1503	30.5	31.0	30.9	31.0	31.5	30.5
1504	33.1	30.2 [a]	33.0	33.6	32.6	32.2
1505	34.3	33.2	33.2	34.5	34.7	35.9
1506	25.4	25.5	26.1	26.7	25.9	27.1
1507	31.6 [a]	33.9	35.0	32.0 [a]	33.0	33.4
1508	30.6	30.3	29.9	30.2	30.6	30.5
1509	26.7 [a]	27.3	28.7	27.6	28.3	28.3
1510	31.2	29.5 [a]	29.5	28.8	30.0	29.1
1511	31.7	33.7	30.3 [a]	29.5	30.2	30.0
1512	27.0	28.4	30.6	27.2 [a]	28.0	27.9
1513	32.8	31.9	31.4	31.4	33.0	33.4
1514	27.9	27.7	27.8	28.3	28.6	27.4 [a]
1515	35.4	32.9 [a]	32.3	31.6	32.2	30.7 [a]
1516	25.3	25.9	26.7	26.5	29.2	28.9
1517	29.6 [a]	31.1	30.5	30.2	31.1	30.6
1518	29.9	30.4	30.3	30.7	30.1	29.3
1519	28.9	28.2	29.2	31.1	29.7 [a]	29.0

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
1520	22.6	23.6	23.8	22.6 [a]	23.1	23.6	23.3
1601	25.4	26.7	26.6	27.6	28.3	29.2	28.9
1602	23.1	22.6	23.5	24.8	24.2	25.4	24.8
1603	24.3	26.6	26.8	27.3	27.1	26.7	26.9
1604	24.3	26.2	26.3	27.0	27.0	24.6 [a]	27.6
1605	21.7	21.2	21.7	22.7	22.2	22.6	24.6
1606	23.3	24.1	23.1	24.1	24.9	24.2	24.0
1607	24.2	24.2	23.8	25.0	25.7	26.0	27.3
1608	23.6	25.2	25.1	25.7	26.4	23.6 [a]	26.3
1609	23.3	23.5	22.8	23.8	24.5	24.1	27.1
1610	23.1	25.2	25.7	26.1	26.1	26.5	28.3
1611	22.4	22.1	23.5	25.0	24.0	25.3	26.3
1612	23.1	26.1	26.2	27.2	27.2	26.5	26.8
1613	26.5	28.5	28.2	29.0	28.9	29.3	30.8
1614	23.9	25.0	25.0	26.8	27.1	27.5	30.6
1615	21.9	23.7	23.8	24.4	24.2	25.4	25.2
1616	24.0	25.3	25.0	26.1	26.8	27.8	28.4
1617	24.3	25.2	25.1	26.0	26.4	27.9	29.2
1618	24.5	24.0	24.2	25.0	25.3	25.5	25.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
1520	25.5	25.4	27.7	27.9	25.4 [a]	26.0	26.6
1601	30.5	32.4	29.4 [a]	30.2	30.5	32.2	34.5
1602	24.6	25.8	25.3	25.0	25.1	25.1	25.0
1603	28.8	29.3	28.1	26.1 [a]	27.8	28.6	30.1
1604	28.8	28.2	28.9	30.7	30.8	31.2	29.9 [a]
1605	24.8	24.7	25.2	26.2	25.1 [a]	24.9	27.7
1606	23.6	25.1	24.9	25.4	24.5	24.5	25.6
1607	25.5 [a]	26.7	27.4	27.5	27.9	27.9	27.6
1608	26.5	29.2	29.2	26.3 [a]	27.8	28.3	31.2
1609	25.3 [a]	27.0	28.8	29.3	29.6	29.6	27.9 [a]
1610	28.1	28.6	27.4	28.8	29.2	28.2	29.4
1611	28.4	31.1	29.8 [a]	30.1	29.0	30.3	29.3
1612	27.1	29.8	31.3	31.2	31.0	29.1 [a]	30.7
1613	31.4	32.1	30.9	30.7	31.3	32.0	32.6
1614	31.1	30.2	29.8	30.2	30.8	29.9	32.0
1615	25.0	25.8	25.8	26.0	25.7	25.8	26.2
1616	29.4	32.4	29.9 [a]	30.9	31.9	31.5	33.1
1617	26.9 [a]	29.6	31.1	31.6	29.9 [a]	28.0 [a]	31.2
1618	25.7	27.1	26.5	27.4	27.9	28.1	28.7

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date					
	32	36	39	43	44	45
1520	26.3	26.1	25.2	25.1	26.4	26.4
1601	33.7	32.6	35.7	36.2	34.7 [a]	32.6 [a]
1602	24.9	24.9	25.4	25.3	25.7	25.9
1603	31.8	28.4 [a]	29.3	30.4	30.9	31.5
1604	28.6 [a]	29.3	31.9	29.8 [c]	29.0	28.4
1605	28.8	26.2 [a]	25.8	28.6	29.1	29.4
1606	26.5	26.7	26.5	28.3	29.7	29.2
1607	27.7	26.9	28.9	29.3	27.7 [a]	26.0 [a]
1608	31.5	30.5	32.2	29.6 [a]	28.4	29.5
1609	28.4	30.0	31.3	27.7 [a]	29.0	29.1
1610	30.9	29.9	31.5	30.1 [a]	29.5	30.0
1611	28.3	28.0	29.3	28.6	28.7	28.8
1612	32.7	30.2	30.1	31.7	32.7	33.2
1613	32.4	32.8	33.8	34.0	35.5	35.0
1614	34.0	31.9 [a]	32.0	31.8	33.5	34.5
1615	26.5	26.5	26.6	26.7	27.2	27.3
1616	34.4	31.8 [a]	34.4	34.1	32.5 [a]	32.1
1617	32.4	29.9 [a]	32.7	33.4	31.3 [a]	30.0
1618	28.0	28.8	28.4 E[b]	-	-	-

E = Exclude
[a] [RC:Value Confirmed]
[b] [FC:Value excluded - animal found dead]
[c] [RC:value confirrmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
1619	24.4	24.6	24.7	24.9	25.2	26.1	26.5
1620	23.7	25.7	23.8 [a]	25.1	25.5	26.0	25.3
Mean	24.25	25.40	25.20	25.99	26.20	26.49	27.22
SD	1.37	1.81	1.67	1.73	1.85	1.86	1.94
N	40	40	40	40	40	40	40

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
1619	26.5	27.8	27.4	26.8	27.6	28.4	28.8
1620	25.1	25.5	27.2	28.3	26.4 [a]	27.1	29.9
Mean	27.49	28.46	28.46	28.61	28.70	28.71	29.62
SD	2.12	2.22	1.94	2.12	2.25	2.13	2.43
N	40	40	40	40	40	40	40

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date					
	32	36	39	43	44	45
1619	27.4 [a]	28.1	30.0	29.6	30.3	28.6 [a]
1620	32.1	28.4 [a]	30.2	30.9	31.6	32.2
Mean	29.94	29.48	30.21	30.08	30.44	30.22
SD	2.83	2.40	2.63	2.56	2.43	2.50
N	40	40	39	39	39	39

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2501	24.2	26.1	26.8	27.2	26.0 [a]	28.6	27.7
2502	24.0	25.4	25.8	27.0	26.1	28.3	29.7
2503	24.9	25.0	23.5 [a]	25.3	25.5	26.3	25.9
2504	27.2	28.8	28.5	28.3	27.8	28.7	28.9
2505	26.1	28.2	26.7 [a]	28.5	28.3	28.0	29.0
2506	24.7	25.1	25.3	26.0	25.5	28.1	28.9
2507	22.8	25.3	24.4	25.9	26.2	25.9	25.7
2508	23.3	23.8	23.9	25.2	24.2	24.2	24.8
2509	24.4	27.0	25.6	26.2	25.1 [a]	27.5	28.1
2510	24.4	26.6	26.9	27.8	28.1	28.5	28.2
2511	23.3	27.0	25.3 [a]	26.4	26.2	27.4	26.1 [a]
2512	25.0	25.5	25.3	26.9	27.3	28.1	27.0
2513	23.1	25.9	26.3	26.6	26.7	26.0	26.9
2514	24.3	27.0	26.7	25.8	26.6	26.3	28.7
2515	23.1	24.3	24.2	25.3	25.6	25.8	25.9
2516	23.3	23.2	24.1	25.7	25.4	25.5	26.5
2517	24.5	26.0	25.0	26.2	25.9	26.1	27.1
2518	24.1	26.4	27.3	28.4	27.1 [a]	27.9	30.5
2519	25.8	30.6	29.3	27.9 [a]	28.1	31.5	33.6

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2501	28.6	31.0	31.5	30.6	29.8	30.3	32.6
2502	28.6	29.5	30.2	31.1	30.2	31.8	32.9
2503	25.6	27.0	28.5	28.7	28.4	27.3	27.0
2504	31.5	33.3	31.0 [a]	31.8	32.0	30.9	32.9
2505	32.3	34.6	30.8 [a]	30.8	29.8	30.5	30.2
2506	27.0 [a]	28.5	30.3	30.5	31.6	31.7	28.4 [a]
2507	26.5	27.7	28.5	27.5	27.5	28.2	27.7
2508	25.9	27.3	25.7 [a]	27.1	27.1	27.3	26.6
2509	25.5 [a]	28.6	29.0	29.4	29.8	29.9	29.9
2510	28.2	30.7	31.0	30.4	30.3	30.0	29.9
2511	26.9	28.7	29.9	30.1	28.3 [a]	28.7	30.1
2512	27.4	29.6	28.7	29.7	28.7	29.2	30.9
2513	27.5	27.8	29.6	30.7	30.7	30.1	29.4
2514	29.8	28.0 [a]	29.5	31.0	31.1	31.9	29.0 [a]
2515	27.8	27.4	29.4	30.9	30.3	31.2	28.8 [a]
2516	27.5	27.4	27.9	28.1	28.3	28.5	27.8
2517	26.4	27.7	28.3	27.5	28.4	28.2	27.6
2518	30.2	30.5	32.3	32.9	31.7	32.7	32.0
2519	30.5 [a]	34.9	37.2	36.0	33.0 [a]	33.3	32.1

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date					
	32	36	39	43	44	45
2501	33.8	31.1 [a]	30.7	34.2	34.5	35.2
2502	34.0	32.0 [a]	31.3	32.4	33.2	33.6
2503	28.0	27.1	28.7	28.7	28.2	28.4
2504	33.3	32.1	33.7	33.5	35.2	35.0
2505	34.2	35.6	31.6 [a]	31.4	33.0	33.1
2506	29.1	29.9	31.0	30.1	29.7	30.2
2507	27.7	27.5	27.5	29.5	30.2	30.7
2508	27.4	26.5	26.9	26.6	27.9	27.4
2509	29.2	29.2	31.2	31.3	31.0	29.2 [a]
2510	29.8	29.8	29.8	30.5	30.4	30.1
2511	30.6	28.8 [a]	28.2	28.1	28.5	28.6
2512	32.3	29.6 [a]	29.7	32.5	34.1	34.2
2513	28.7	29.9	30.7	28.9 [a]	30.1	30.4
2514	27.5 [a]	31.4	33.1	28.9 [a]	30.8	30.9
2515	28.0	30.8	32.0	28.0 [a]	31.8	30.7
2516	29.2	29.3	29.2	28.7	30.2	30.2
2517	27.5	27.7	28.6	27.6	28.9	29.1
2518	34.2	34.8	32.0 [a]	31.7	33.2	33.6
2519	32.7	33.2	37.0	38.1	38.7	36.9 [a]

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2520	23.4	24.1	22.4	24.1	24.8	26.3	28.5
2601	24.6	25.8	26.0	26.8	27.1	27.1	28.1
2602	25.8	29.1	29.2	28.5	28.4	28.2	29.4
2603	24.8	25.7	25.7	26.8	27.2	27.7	27.5
2604	23.0	23.6	24.1	24.2	25.1	24.0 [a]	24.1
2605	23.5	25.4	23.9 [a]	24.6	25.0	25.9	25.5
2606	20.9	23.8	22.9	24.1	24.0	25.2	26.5
2607	21.1	22.2	22.1	22.8	22.7	23.2	24.2
2608	25.8	27.5	28.4	29.4	30.3	31.0	30.1
2609	24.6	24.6	25.5	26.1	27.3	27.9	27.4
2610	25.6	28.8	28.7	29.4	29.5	29.7	30.1
2611	26.9	25.5 [a]	26.2	26.7	25.9	27.8	29.7
2612	26.0	25.0	25.8	26.1	26.1	26.4	27.1
2613	23.2	22.7	23.5	24.1	23.3	23.3	24.5
2614	22.7	25.1	24.9	25.2	25.8	26.6	25.6
2615	22.4	23.0	23.1	23.9	24.5	24.7	24.0
2616	24.6	26.4	25.7	26.9	27.3	27.7	27.5
2617	20.8	21.4	21.3	21.5	21.6	23.2	24.5
2618	24.1	28.9	27.5	28.5	26.9 [a]	27.1	29.2

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2520	27.5	28.8	28.7	29.6	28.5	28.4	29.9
2601	30.6	32.3	30.4 [a]	31.2	29.6 [a]	29.8	32.9
2602	29.3	31.1	31.4	31.5	30.7	30.5	32.4
2603	28.3	30.3	32.2	31.9	31.0	29.5 [a]	29.2
2604	25.2	25.4	25.2	26.0	27.5	28.1	26.7 [a]
2605	27.1	29.4	28.0 [a]	28.7	28.8	27.6	26.7
2606	24.9 [a]	26.0	25.8	28.1	27.9	28.0	28.1
2607	24.2	24.8	25.3	26.0	24.6 [a]	25.4	26.3
2608	33.7	35.8	32.8 [a]	35.1	36.1	36.0	35.6
2609	28.2	28.4	29.5	28.6	29.4	28.3	29.9
2610	32.8	32.0	33.9	34.2	35.6	35.6	32.3 [a]
2611	27.8 [a]	27.1	29.3	29.9	30.3	30.6	27.9 [a]
2612	27.1	28.6	28.6	29.3	28.7	28.2	29.1
2613	24.9	25.4	25.0	25.7	24.8	26.5	24.6 [a]
2614	26.1	28.1	29.3	29.0	29.1	26.8 [a]	29.3
2615	25.7	27.8	26.1 [a]	26.9	27.6	26.3 [a]	27.2
2616	27.7	29.5	29.7	29.5	29.8	29.6	29.0
2617	23.8	25.7	25.7	25.8	24.9	25.3	25.9
2618	30.4	32.6	29.0 [a]	30.5	30.9	31.5	30.2

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date					
	32	36	39	43	44	45
2520	31.6	30.0 [a]	32.0	32.6	32.7	31.3 [a]
2601	34.9	32.2 [a]	31.3	30.4	31.6	32.5
2602	31.0 [a]	31.8	30.9	31.6	31.9	31.6
2603	30.0	31.2	32.7	32.9	31.8	31.6
2604	27.3	27.8	28.5	25.9 [a]	26.6	25.7
2605	27.6	28.1	27.9	27.7	28.6	27.0 [a]
2606	29.7	28.8	29.2	28.9	30.1	28.4 [a]
2607	27.4	26.5	28.0	27.7	26.7	26.6
2608	34.3	37.4	38.8	35.4 [a]	37.4	38.3
2609	31.8	31.7	30.5	30.5	31.3	31.7
2610	35.2	36.3	32.8 [a]	36.0	37.2	38.2
2611	29.8	30.9	29.3 [a]	29.1	29.7	28.2 [a]
2612	28.7	28.2	29.3	29.2	30.0	28.7 [a]
2613	24.4	24.5	24.6	24.5	25.2	24.5
2614	30.1	26.5 [a]	30.4	31.5	31.6	30.5
2615	28.4	27.1 [a]	25.7 [a]	25.4	26.9	27.3
2616	29.4	29.8	30.1	29.6	30.6	30.8
2617	26.0	25.1	25.0	26.0	27.2	26.5
2618	29.2	30.1	30.5	31.2	31.0	30.0

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2619	23.6	24.1	22.8	24.5	25.0	25.2	24.9
2620	23.2	24.4	24.1	24.6	24.7	24.9	25.0
Mean	24.08	25.61	25.37	26.14	26.11	26.80	27.32
SD	1.47	2.01	1.97	1.78	1.75	1.93	2.14
N	40	40	40	40	40	40	40
%Diff	-0.69	0.83	0.65	0.56	-0.37	1.17	0.37

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2619	24.9	26.0	26.6	27.4	27.4	27.0	26.8
2620	25.7	27.2	29.6	29.4	30.6	30.9	28.6 [a]
Mean	27.74	29.06	29.29	29.73	29.52	29.54	29.36
SD	2.39	2.68	2.52	2.38	2.39	2.43	2.38
N	40	40	40	40	40	40	40
%Diff	0.92	2.13	2.92	3.92	2.87	2.89	-0.87

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: pretreatment and dosing period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date					
	32	36	39	43	44	45
2619	27.8	27.1	27.1	27.3	27.7	26.9
2620	30.4	32.1	29.0 [a]	29.3	30.8	31.1
Mean	30.06	29.99	30.16	30.09	30.91	30.62
SD	2.68	2.92	2.79	2.94	3.01	3.25
N	40	40	40	40	40	40
%Diff	0.40	1.73	-0.15	0.03	1.53	1.32

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	45	46	50	53	57	60	64
1101	38.1	37.6	38.2	37.8	38.1	38.2	38.9
1102	36.9	36.8	36.8	36.7	38.5	39.2	39.3
1103	38.5	36.8 [a]	38.2	37.4	38.5	38.3	38.6
1104	39.5	39.1	39.1	39.3	39.1	40.9	41.0
1105	36.4	35.9	36.0	36.0	36.6	36.6	37.1
1106	41.3	40.8	41.3	41.9	40.6	42.3	41.8
1107	38.8	38.0	38.0	38.1	37.5	37.9	39.6
1108	40.4	39.4	39.5	39.7	39.4	41.6	41.6
1109	38.9	38.6	38.3	38.8	38.3	39.7	39.9
1110	43.6	42.7	43.5	43.0	42.1	43.1	43.1
1111	38.6	37.8	37.5	38.5	37.6	38.3	38.9
1112	49.1	48.7	47.3	49.1	48.6	50.0	50.6
1113	44.5	43.6	44.2	44.7	43.7	45.1	44.4
1114	38.8	38.8	38.5	39.0	39.9	40.9	41.7
1115	42.6	41.7	41.4	42.6	41.6	42.8	42.2
1116	41.5	39.4 [a]	40.5	40.3	39.1	39.0	39.9
1117	40.4	39.9	39.7	40.2	40.4	41.3	40.5
1118	40.2	38.6	39.7	39.0	38.6	39.4	38.9
1119	42.4	41.0	41.3	41.8	40.9	42.7	42.7

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date		
	67	71	74
1101	39.3	38.8	38.4
1102	39.4	39.9	40.1
1103	39.2	39.7	40.0
1104	41.0	40.0	41.6
1105	37.4	37.3	37.6
1106	42.8	42.1	42.2
1107	39.3	39.0	39.3
1108	41.3	42.0	41.8
1109	40.1	40.0	41.1
1110	44.7	42.6 [a]	41.7
1111	39.7	40.8	40.1
1112	52.9	52.1	53.1
1113	45.8	45.6	45.6
1114	41.7	42.0	43.8
1115	43.5	44.9	44.4
1116	40.2	40.6	40.0
1117	41.5	41.5	41.5
1118	40.9	40.2	39.7
1119	43.0	43.6	44.8

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul	Day(s) Relative to Start Date						
Group 1	45	46	50	53	57	60	64
1120	42.2	41.7	41.2	42.7	41.1	42.6	42.9
Mean	40.64	39.85	40.01	40.33	40.01	41.00	41.18
SD	2.94	2.92	2.71	3.09	2.67	3.04	2.89
N	20	20	20	20	20	20	20

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date		
	67	71	74
1120	42.4	43.3	42.3
Mean	41.81	41.80	41.96
SD	3.32	3.19	3.36
N	20	20	20

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	45	46	50	53	57	60	64
2101	41.6	40.7	41.2	42.3	41.9	41.6	41.9
2102	38.5	38.5	37.6	38.3	38.2	37.1	38.1
2103	39.3	41.5	41.2	41.2	41.5	40.9	42.5
2104	39.0	39.3	38.7	38.8	39.0	38.4	39.8
2105	38.8	38.1	38.9	36.6 [a]	37.4	36.1	39.1
2106	37.8	37.8	39.8	38.1 [a]	38.3	38.0	39.5
2107	41.8	42.7	41.2	40.5	40.6	40.8	40.7
2108	41.3	40.6	39.9	38.7	39.6	39.8	39.8
2109	41.7	40.9	40.6	40.9	40.0	39.3	41.1
2110	37.1	36.3	36.2	35.9	36.0	36.0	36.9
2111	39.8	39.5	39.0	39.3	39.6	39.8	40.0
2112	41.0	41.8	39.9 [a]	40.0	40.6	40.3	41.4
2113	39.1	39.2	39.0	39.3	39.4	39.8	39.6
2114	36.4	37.7	36.7	36.2	36.1	38.8	36.9 [a]
2115	39.2	39.9	40.0	39.2	39.4	39.9	40.2
2116	38.9	38.4	37.8	38.9	38.6	39.7	40.3
2117	39.2	38.7	39.0	38.5	40.1	39.5	39.7
2118	41.9	42.7	41.9	41.6	42.3	42.2	43.5
2119	37.7	37.5	37.0	36.7	37.1	37.8	38.3

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date		
	67	71	74
2101	42.7	41.8	41.8
2102	37.6	37.5	37.7
2103	43.4	42.1	42.9
2104	38.2	39.9	38.7
2105	37.2 [a]	38.7	38.5
2106	37.7 [a]	38.3	37.9
2107	42.5	40.6 [a]	41.0
2108	40.4	40.5	40.2
2109	39.9	40.7	41.1
2110	37.4	38.0	37.0
2111	40.3	40.0	39.7
2112	41.6	41.0	41.2
2113	39.7	39.3	40.0
2114	37.7	37.2	38.6
2115	40.1	40.1	40.9
2116	41.0	40.1	41.4
2117	39.4	39.9	39.4
2118	44.3	45.1	45.4
2119	37.2	37.7	36.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	45	46	50	53	57	60	64
2120	37.7	38.2	38.8	39.5	40.0	39.3	40.9
Mean	39.39	39.50	39.22	39.03	39.29	39.26	40.01
SD	1.67	1.80	1.60	1.78	1.75	1.65	1.68
N	20	20	20	20	20	20	20
%Diff	-3.06	-0.87	-1.97	-3.24	-1.81	-4.24	-2.84

Appendix 6

Individual body weights: recovery period

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date		
	67	71	74
2120	39.7	40.1	40.7
Mean	39.90	39.93	40.05
SD	2.17	1.84	2.08
N	20	20	20
%Diff	-4.56	-4.47	-4.54

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	45	46	50	53	57	60	64
1601	32.6 [a]	31.7	32.4	32.1	34.0	35.9	33.3 [a]
1602	25.9	26.3	26.8	28.9	28.6	26.3 [a]	26.0
1603	31.5	31.0	30.4	32.2	32.0	29.8 [a]	29.7
1604	28.4	28.3	29.5	29.2	30.6	32.1	29.7 [a]
1605	29.4	30.0	26.8 [a]	29.1	28.7	30.1	30.1
1606	29.2	26.6 [a]	27.9	27.9	28.8	30.1	29.7
1607	26.0 [a]	26.6	26.4	28.4	27.9	26.8	26.4
1608	29.5	29.4	29.5	31.0	32.6	30.5 [a]	32.1
1609	29.1	29.7	31.1	28.4 [a]	28.3	27.5	29.6
1610	30.0	30.5	30.4	32.7	31.8	31.9	32.4
1611	28.8	28.7	30.2	31.6	31.8	30.7	30.3
1612	33.2	33.2	30.2 [a]	33.3	34.2	31.3 [a]	31.1
1613	35.0	34.3	35.0	35.0	34.1	34.1	34.6
1614	34.5	34.2	35.2	32.6 [a]	35.5	37.5	32.6 [a]
1615	27.3	26.6	26.9	27.7	27.4	27.2	27.1
1616	32.1	32.0	32.2	32.3	32.6	35.5	36.8
1617	30.0	29.7	29.8	33.2	34.1	31.1 [a]	31.0
1619	28.6 [a]	29.0	29.2	28.7	29.2	30.1	30.5

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date		
	67	71	74
1601	32.1	35.3	36.6
1602	25.8	25.7	26.3
1603	32.1	33.6	30.2 [a]
1604	31.1	33.5	31.9 [a]
1605	29.1	28.9	30.8
1606	28.4 [a]	28.3	28.0
1607	26.5	28.3	29.3
1608	33.9	30.2 [a]	33.0
1609	31.3	29.7 [a]	28.3 [a]
1610	35.2	32.5 [a]	32.6
1611	31.5	32.2	31.9
1612	34.3	35.3	34.4
1613	35.5	37.4	38.2
1614	34.4	36.7	38.4
1615	27.0	27.8	27.0
1616	34.9 [a]	37.6	38.4
1617	30.7	33.8	36.0
1619	31.5	33.6	31.3 [a]

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date						
	45	46	50	53	57	60	64
1620	32.2	32.1	32.7	30.3 [a]	32.5	33.9	31.2 [a]
Mean	30.17	29.99	30.14	30.77	31.30	31.18	30.75
SD	2.60	2.51	2.58	2.19	2.54	3.13	2.65
N	19	19	19	19	19	19	19

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 1	Day(s) Relative to Start Date		
	67	71	74
1620	31.7	33.9	34.2
Mean	31.42	32.33	32.46
SD	2.96	3.49	3.84
N	19	19	19

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	45	46	50	51	52	53	57
2601	32.5	32.2	31.9	-	-	32.6	33.2
2602	31.6	33.2	31.6 [a]	-	-	32.4	33.6
2603	31.6	33.5	31.3 [a]	-	-	32.2	32.3
2604	25.7	27.1	26.3	-	-	27.4	27.1
2605	27.0 [a]	28.8	28.0	-	-	27.9	27.0
2606	28.4 [a]	29.4	28.8	-	-	29.5	30.7
2607	26.6	27.6	27.2	-	-	26.4	27.0
2608	38.3	40.8	39.5	-	-	35.4 [a]	39.5
2609	31.7	31.1	30.8	-	-	32.2	33.1
2610	38.2	39.3	34.9 [a]	36.0	37.0	36.9	39.5
2611	28.2 [a]	29.5	27.8 [a]	-	-	27.8	30.7
2612	28.7 [a]	30.0	29.7	-	-	29.3	29.1
2613	24.5	27.4	25.7 [a]	-	-	27.8	26.5 [a]
2614	30.5	29.0 [a]	29.7	-	-	29.6	29.3
2615	27.3	28.2	27.3	-	-	29.1	28.7
2616	30.8	31.2	30.2	-	-	30.5	31.7
2617	26.5	27.9	25.3 [a]	-	-	26.0	25.3
2618	30.0	31.5	30.8	-	-	32.7	30.2 [a]
2619	26.9	28.4	27.1 [a]	-	-	26.9	27.2

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date				
	60	64	67	71	74
2601	33.2	32.9	32.3	33.0	33.6
2602	35.0	33.1 [a]	33.3	34.8	34.2
2603	32.0	32.5	31.3	34.8	36.0
2604	28.6	28.3	27.6	28.6	27.2 [a]
2605	28.6	28.4	28.3	27.6	27.2
2606	31.7	29.6 [a]	30.6	30.2	31.6
2607	25.8 [a]	26.5	27.2	28.8	28.9
2608	41.8	36.7 [a]	41.4	43.1	37.1 [a]
2609	30.0 [a]	30.6	32.6	33.7	31.7 [a]
2610	36.1 [a]	39.7	39.4	36.2 [a]	38.9
2611	31.6	28.9 [a]	31.8	33.3	31.3 [a]
2612	29.6	30.4	29.3	30.0	29.3
2613	26.8	26.3	26.1	26.7	26.0
2614	30.1	32.0	29.4 [a]	33.1	33.0
2615	27.8	29.0	30.7	30.6	27.7 [a]
2616	32.3	33.1	31.9	31.2	30.5
2617	25.9	26.6	27.3	27.0	26.2
2618	31.1	33.1	30.6 [a]	31.1	31.3
2619	28.3	30.0	30.9	28.7 [a]	27.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	45	46	50	51	52	53	57
2620	31.1	32.8	32.4	-	-	30.0 [a]	29.3
Mean	29.81	30.95	29.82	36.00	37.00	30.13	30.55
SD	3.68	3.70	3.38	-	-	2.97	3.90
N	20	20	20	1	1	20	20
%Diff	-1.22	3.17	-1.07	-	-	-2.07	-2.40

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: recovery period

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date				
	60	64	67	71	74
2620	32.0	32.7	31.1 [a]	31.3	34.2
Mean	30.92	31.02	31.16	31.69	31.19
SD	3.78	3.39	3.74	3.82	3.71
N	20	20	20	20	20
%Diff	-0.85	0.89	-0.85	-1.98	-3.92

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2201	31.6	33.3	32.6	33.9	34.0	33.9	34.2
2202	33.3	35.7	34.9	35.7	36.0	36.6	36.7
2203	31.2	33.3	32.8	33.8	33.5	33.9	34.9
2204	32.1	34.6	34.3	35.3	35.1	35.3	35.9
2205	32.3	35.2	33.8	34.2	35.1	36.1	36.0

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2201	34.7	35.7	35.0	34.5	34.9	35.4	34.8
2202	37.8	38.2	37.9	38.9	39.3	39.3	39.0
2203	35.4	36.5	36.4	37.1	37.3	36.9	36.8
2204	36.9	38.5	38.1	38.6	39.7	38.5	38.2
2205	36.2	37.5	37.3	36.3	36.7	37.4	37.3

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	32	36	39	43	44	45	46
2201	35.9	35.5	36.9	35.4	35.9	36.0	35.7
2202	40.1	39.7	40.7	39.3	40.4	40.5	40.5
2203	37.5	37.0	38.5	36.6 [a]	37.7	37.9	37.9
2204	39.5	38.8	39.0	37.4	39.9	38.9	39.8
2205	37.8	37.7	38.3	36.2 [a]	37.4	37.7	38.1

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	50	53	57	60	64	67	71
2201	35.0	35.9	34.9	34.8	35.8	35.6	35.9
2202	40.1	40.6	39.1	39.8	40.6	40.1	41.1
2203	38.3	38.0	37.5	38.8	40.7	40.7	41.3
2204	40.1	40.3	37.5 [a]	38.7	39.7	39.6	39.7
2205	37.8	37.9	36.7	37.5	38.8	37.8	38.4

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Male Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date 74
2201	34.3 [a]
2202	39.3 [a]
2203	40.7
2204	39.7
2205	37.9

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	-7	1	2	3	4	8	11
2701	24.5	25.9	25.1	25.9	26.1	26.6	26.4
2702	25.2	25.7	25.7	25.6	26.1	27.1	27.6
2703	22.9	22.8	23.4	24.2	24.5	24.1	24.4
2704	22.3	22.4	22.3	23.4	23.7	24.5	25.1
2705	21.2	22.4	20.9	21.5	22.4	23.3	23.3

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	15	18	22	23	24	25	29
2701	27.1	28.3	29.4	28.0 [a]	28.5	28.7	28.2
2702	27.5	28.6	28.3	30.0	29.6	30.2	30.2
2703	24.9	27.0	26.7	26.0	25.4	25.9	25.5
2704	23.6 [a]	23.9	25.0	25.5	25.9	25.4	24.5
2705	24.6	25.1	25.2	25.2	25.5	26.2	26.3

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	32	36	39	43	44	45	46
2701	28.5	28.3	27.7	28.0	29.3	29.3	30.7
2702	30.8	30.4	30.9	28.9 [a]	32.0	31.6	31.8
2703	28.4	28.7	27.0 [a]	26.5	27.1	28.0	29.7
2704	24.5	26.5	27.6	24.3 [a]	26.4	25.9	26.6
2705	25.8	26.8	27.5	25.6	28.2	27.0 [a]	28.3

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date						
	50	53	57	60	64	67	71
2701	29.4 [a]	29.7	29.5	31.2	31.3	30.9	31.9
2702	31.6	31.4	31.2	31.0	32.2	31.0	31.4
2703	29.3	28.0 [a]	28.0	30.0	30.8	28.2 [a]	28.1
2704	26.8	27.8	26.3 [a]	26.4	26.3	28.0	28.3
2705	28.0	27.7	27.3	28.1	28.0	28.8	29.2

[a] [RC:Value Confirmed]

Appendix 6

Individual body weights: immunogenicity animals

513351
Sex: Female Bodyweight (g)

70 ul Group 2	Day(s) Relative to Start Date 74
2701	31.9
2702	29.9 [a]
2703	28.0
2704	25.9 [a]
2705	28.2

[a] [RC:Value Confirmed]

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 1 → 45
1001	3.6
1002	4.1
1003	3.3
1004	3.0
1005	4.1
1006	4.7
1007	1.6
1008	3.8
1009	4.6
1010	4.7
1011	5.3
1012	6.1
1013	6.4
1014	5.3
1015	3.5
1016	2.0
1017	5.1
1018	3.3
1019	4.4

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 1 → 45
1020	4.9
1101	7.1
1102	2.6
1103	4.1
1104	3.7
1105	3.5
1106	5.2
1107	3.7
1108	5.9
1109	3.9
1110	5.5
1111	3.9
1112	8.7
1113	6.1
1114	3.1
1115	6.2
1116	5.5
1117	6.1
1118	5.0

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 1 → 45
1119	6.4
1120	6.9
Mean	4.67
SD	1.47
N	40

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 1 → 45
2001	2.7
2002	4.7
2003	4.1
2004	1.9
2005	2.9
2006	5.4
2007	3.7
2008	5.5
2009	5.0
2010	5.2
2011	3.4
2012	4.4
2013	4.0
2014	3.9
2015	5.2
2016	3.6
2017	4.3
2018	4.9
2019	5.4

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 1 → 45
2020	6.0
2101	5.6
2102	5.1
2103	1.6
2104	4.3
2105	2.5
2106	2.2
2107	5.4
2108	4.6
2109	5.3
2110	2.5
2111	4.8
2112	3.7
2113	5.0
2114	3.1
2115	5.0
2116	6.8
2117	4.4
2118	5.8

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 1 → 45
2119	4.2
2120	2.3
Mean	4.26
SD	1.24
N	40

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 1 → 45
1501	7.9
1502	6.5
1503	1.4
1504	2.6
1505	7.1
1506	3.2
1507	5.7
1508	4.7
1509	3.9
1510	2.9
1511	3.5
1512	4.0
1513	7.7
1514	2.0
1515	4.0
1516	4.3
1517	4.0
1518	3.3
1519	3.7

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 1 → 45
1520	2.8
1601	5.9
1602	3.3
1603	4.9
1604	2.2
1605	8.2
1606	5.1
1607	1.8
1608	4.3
1609	5.6
1610	4.8
1611	6.7
1612	7.1
1613	6.5
1614	9.5
1615	3.6
1616	6.8
1617	4.8
1619	4.0

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 1 → 45
1620	6.5
Mean	4.79
SD	1.95
N	39

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 1 → 45
2501	9.1
2502	8.2
2503	3.4
2504	6.2
2505	4.9
2506	5.1
2507	5.4
2508	3.6
2509	2.2
2510	3.5
2511	1.6
2512	8.7
2513	4.5
2514	3.9
2515	6.4
2516	7.0
2517	3.1
2518	7.2
2519	6.3

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 1 → 45
2520	7.2
2601	6.7
2602	2.5
2603	5.9
2604	2.1
2605	1.6
2606	4.6
2607	4.4
2608	10.8
2609	7.1
2610	9.4
2611	2.7
2612	3.7
2613	1.8
2614	5.4
2615	4.3
2616	4.4
2617	5.1
2618	1.1

Appendix 7

Individual body weight gains (g): pretreatment and dosing period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 1 → 45
2619	2.8
2620	6.7
Mean	5.02
SD	2.37
N	40

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 45 → 74
1101	0.3
1102	3.2
1103	1.5
1104	2.1
1105	1.2
1106	0.9
1107	0.5
1108	1.4
1109	2.2
1110	-1.9
1111	1.5
1112	4.0
1113	1.1
1114	5.0
1115	1.8
1116	-1.5
1117	1.1
1118	-0.5
1119	2.4

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 45 → 74
1120	0.1
Mean	1.32
SD	1.66
N	20

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 45 → 74
2101	0.2
2102	-0.8
2103	3.6
2104	-0.3
2105	-0.3
2106	0.1
2107	-0.8
2108	-1.1
2109	-0.6
2110	-0.1
2111	-0.1
2112	0.2
2113	0.9
2114	2.2
2115	1.7
2116	2.5
2117	0.2
2118	3.5
2119	-0.8

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Male Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 45 → 74
2120	3.0
Mean	0.66
SD	1.52
N	20

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 45 → 74
1601	4.0
1602	0.4
1603	-1.3
1604	3.5
1605	1.4
1606	-1.2
1607	3.3
1608	3.5
1609	-0.8
1610	2.6
1611	3.1
1612	1.2
1613	3.2
1614	3.9
1615	-0.3
1616	6.3
1617	6.0
1619	2.7

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 1	Day(s) Relative to Start Date 45 → 74
1620	2.0
Mean	2.29
SD	2.21
N	19

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 45 → 74
2601	1.1
2602	2.6
2603	4.4
2604	1.5
2605	0.2
2606	3.2
2607	2.3
2608	-1.2
2609	0.0
2610	0.7
2611	3.1
2612	0.6
2613	1.5
2614	2.5
2615	0.4
2616	-0.3
2617	-0.3
2618	1.3
2619	1.0

Appendix 7

Individual body weight gains (g): recovery period

513351
Sex: Female Bodyweight Gain (Interval)

70 ul Group 2	Day(s) Relative to Start Date 45 → 74
2620	3.1
Mean	1.39
SD	1.45
N	20

Appendix 8

Individual food consumption

Explanation page

Abbreviation	Description
AFE	Animal found with no food during measurement interval, excluded
AFNF	Animal found with no food during measurement interval
ANH	Animal found with no hopper during measurement interval
ANIC	Animal not in cage or in incorrect cage during measurement
ANW	Animal found with no water access during measurement intervals
ANWB	Animal found with no water bottle during measurement interval
AVS	Suspected aberrant value
AWE	Animal found with no water in bottle during measurement interval, excluded
FSG	Food supplementation given during interval, included in feed weight
FSNC	Food supplementation given during interval, value not calculable
NC	Not calculable
OA	Omitted activity
POWF	Powdered food
REHO	Animal rehoused during measurement interval
REPL	Animal replaced during measurement interval
RC	Result comment
SPIL	Spilled food (by animal)
TERR	Technical error
UPTD	Unable to perform due to technical difficulty
WETF	Wet or contaminated food (in container)
X	Excluded from mean/statistical analysis
-	Animal deceased, collection not scheduled to be performed or unable to calculate

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

Appendix 8

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
1	1	6	4	6	6	7	6	6
2	1	6	4	7	6	6	5	6
3	1	5	4	5	5	6	6	6
4	1	6	7	7	6	6	7	8
5	1	5	5	7	6	6	7	6
6	1	6	5	6	6	6	6	6
7	1	5	4	6	6	6	6	5
8	1	6	5	6	6	6	6	6
9	1	5	5	6	6	6	6	6
10	1	6	4	10	6	6	6	6
11	1	6	6	7	7	8	7	7
12	1	5	5	7	7	7	7	8
13	1	6	4	7	6	6	8	7
14	1	5	6	6	6	6	6	7
15	1	6	6	7	6	7	7	7
16	1	7	5	8	6	6	6	7
17	1	6	5	5	6	6	6	6
18	1	5	6	6	7	6	6	7
19	1	6	4	6	6	7	6	6

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
1	1	6	6	6	6	5
2	1	6	6	6	6	5
3	1	5	6	6	6	7
4	1	7	7	6	6	7
5	1	6	7	6	6	7
6	1	6	6	6	6	6
7	1	6	6	5	6	6
8	1	6	6	6	7	6
9	1	6	6	6	6	6
10	1	7	6	6	6	6
11	1	7	8	8	7	7
12	1	6	6	7	6	7
13	1	7	7	7	7	5
14	1	6	7	6	7	7
15	1	7	7	7	6	8
16	1	6	6	6	6	5
17	1	6	6	6	6	7
18	1	7	7	6	6	7
19	1	7	6	6	6	6

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
20	1	6	5	7	7	8	7	8
21	1	5	5	6	6	6	6	7
22	1	6	4	6	6	6	6	6
23	1	5	4	6	6	5	6	5
24	1	7	6	7	7	8	8	8
25	1	5	5	6	5	6	-	5
26	1	6	5	7	7	6	8	9
27	1	6	6	8	7	8	6	8
28	1	5	5	6	6	6	6	6
29	1	6	4	7	6	5	6	6
30	1	6	6	7	7	7	7	8
31	1	5	5	6	5	6	6	6
32	1	7	6	8	7	7	7	8
33	1	6	7	7	7	7	6	11 [a]
34	1	6	5	8	6	6	6	7
35	1	6	5	9	7	9	8	10 [a]
36	1	7	7	8	7	8	8	9
37	1	5	5	7	6	7	6	7
38	1	6	7	7	6	6	6	6

[a] [RC:Value Confirmed]

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
20	1	7	7	7	7	8
21	1	7	7	6	7	7
22	1	6	6	5	6	6
23	1	6	6	5	6	4
24	1	10	8	7	8	9
25	1	6	6	5	5	5
26	1	7	7	7	6	5
27	1	8	7	7	8	7
28	1	6	6	6	6	6
29	1	6	7	6	7	6
30	1	7	7	7	7	6
31	1	6	6	5	6	6
32	1	7	7	7	7	6
33	1	7	7	6	7	6
34	1	6	7	6	6	6
35	1	9	9	7	9	7
36	1	8	8	7	7	8
37	1	6	7	6	6	6
38	1	6	6	6	6	6

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
39	1	6	4	6	6	6	6	8
40	1	6	6	7	6	7	7	7
	Mean	5.8	5.2	6.8	6.1	6.5	6.3	7.0
	SD	0.5	0.9	1.0	0.5	0.8	0.7	1.3
	N	40	40	40	40	40	39	40

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
39	1	6	7	7	7	8
40	1	8	7	8	7	10 [a]
	Mean	6.5	6.5	6.3	6.3	6.5
	SD	1.0	0.8	0.7	0.7	1.2
	N	40	40	40	40	40

[a] [RC:Value Confirmed]

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
41	1	6	5	7	6	6	6	6
42	1	6	4	7	6	6	6	5
43	1	7	5	7	7	7	7	6
44	1	6	5	8	7	7	7	7
45	1	6	4	7	6	6	6	5
46	1	6	3	7	6	7	7	6
47	1	6	6	6	6	6	6	7
48	1	6	5	7	7	7	7	6
49	1	6	5	6	7	6	6	6
50	1	6	6	6	7	7	6	7
51	1	6	5	7	7	7	7	7
52	1	6	6	7	6	6	6	6
53	1	6	6	6	6	7	6	6
54	1	6	5	7	6	6	6	7
55	1	7	5	7	7	7	7	6
56	1	5	5	6	6	7	6	7
57	1	6	5	6	6	6	6	5
58	1	6	6	7	6	7	6	7
59	1	6	4	6	6	6	6	6

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
41	1	6	6	6	6	6
42	1	6	6	6	7	6
43	1	7	7	7	7	7
44	1	7	8	8	8	8
45	1	6	6	5	5	6
46	1	6	7	6	7	6
47	1	6	6	6	6	5
48	1	6	7	6	6	6
49	1	6	6	7	6	11 [a]
50	1	6	6	6	6	7
51	1	8	8	8	8	7
52	1	6	7	7	7	7
53	1	7	6	7	6	7
54	1	7	7	6	7	6
55	1	6	7	6	6	6
56	1	6	7	6	7	8
57	1	7	6	6	6	6
58	1	6	6	7	6	7
59	1	6	6	6	6	5

[a] [RC:Value Confirmed]

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
60	1	6	5	6	6	6	6	5
61	1	6	5	6	6	6	6	6
62	1	6	5	6	5	6	6	6
63	1	6	4	7	7	7	6	6
64	1	6	6	7	6	6	6	6
65	1	6	5	7	6	5	6	5
66	1	5	4	6	7	7	6	6
67	1	5	5	5	5	6	6	6
68	1	6	5	7	7	7	6	7
69	1	6	6	7	7	6	6	6
70	1	6	5	8	6	7	7	6
71	1	6	5	6	6	6	6	6
72	1	6	4	7	7	7	7	6
73	1	6	4	7	7	7	7	6
74	1	5	5	5	6	6	6	5
75	1	6	6	7	6	6	6	5
76	1	5	4	6	5	6	6	5
77	1	6	4	6	7	7	6	6
78	1	6	5	7	6	6	7	5

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
60	1	7	7	7	7	6
61	1	6	6	5	6	6
62	1	6	6	6	6	7
63	1	7	7	7	8	9
64	1	6	6	6	6	7
65	1	5	6	6	6	6
66	1	6	6	6	6	7
67	1	6	6	6	6	7
68	1	7	6	6	6	7
69	1	6	6	6	7	5
70	1	8	7	7	6	8
71	1	6	7	6	6	5
72	1	7	7	7	6	7
73	1	7	7	7	7	6
74	1	6	6	7	8	7
75	1	7	6	5	6	5
76	1	6	6	5	6	5
77	1	7	7	6	6	4
78	1	6	6	6	7	6

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
79	1	6	4	6	6	6	7	8
80	1	6	6	7	7	7	6	7
	Mean	5.9	4.9	6.5	6.2	6.4	6.1	6.1
	SD	0.4	0.8	0.6	0.5	0.5	0.5	0.7
	N	40	40	40	40	40	40	40
	%Diff	2.7	-4.4	-3.4	1.8	-1.4	-2.8	-12.9

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
79	1	6	6	5	6	6
80	1	6	7	6	7	8
	Mean	6.4	6.3	6.2	6.3	6.5
	SD	0.6	0.6	0.6	0.5	1.3
	N	40	40	40	40	40
	%Diff	-2.6	-3.6	-0.8	0.1	1.2

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
86	3	5	4	6	5	6	5	6
87	3	5	4	5	5	6	5	5
88	3	5	5	6	6	6	5	5
89	3	5	4	6	5	5	6	6
90	3	5	4	5	6	5	5	7
91	3	5	5	6	6	5	-	5
92	2	5	6	6	6	6	6	8
93	3	5	5	5	5	6	5	5
94	3	4	5	5	5	5	5	6
95	3	5	4	6	5	7	5	9
96	3	5	5	5	5	6	5	6
97	3	5	5	6	6	6	6	8
98	3	4	3	5	5	5	5	4
99	2	5	5	6	6	6	5	6
Mean		4.7	4.6	5.5	5.4	5.7	5.3	6.2
SD		0.3	0.6	0.5	0.4	0.5	0.4	1.4
N		14	14	14	14	14	13	14

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
86	3	5	6	6	5	6
87	3	5	5	5	6	5
88	3	5	5	6	5	6
89	3	6	6	6	6	6
90	3	6	5	5	5	6
91	3	5	6	6	5	7
92	2	5	5	6	6	7
93	3	6	4	6	6	6
94	3	5	5	5	5	6
95	3	6	5	6	5	5
96	3	6	5	6	5	7
97	3	7	6	6	6	7
98	3	6	4	5	6 n=2	4 n=2
99	2	6	5	5	6	6
Mean		5.5	5.2	5.6	5.5	6.0
SD		0.5	0.5	0.5	0.3	0.8
N		14	14	14	14	14

n = Number of Animals in Cage

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
100	3	5	3	5	5	6	6	5
101	3	5	3	5	6	6	5	6
102	3	5	3	5	5	6	5	6
103	3	5	4	6	6	7	6	6
104	3	5	4	5	6	5	6	6
105	3	5	4	6	6	6	6	6
106	2	5	4	7	6	7	8	5
107	3	5	3	6	6	6	5	5
108	3	5	4	6	6	6	6	6
109	3	5	4	6	6	6	5	6
110	3	4	3	6	5	6	6	6
111	3	5	4	5	5	6	6	5
112	3	5	3	6	5	7	5	5
113	2	4	3	5	5	6	5	6
Mean		4.8	3.5	5.7	5.5	6.1	5.7	5.5
SD		0.3	0.4	0.5	0.3	0.4	0.8	0.4
N		14	14	14	14	14	14	14
%Diff		0.5	-23.0	2.4	2.2	7.3	8.4	-11.3

Appendix 8

Individual food consumption: pretreatment and dosing period

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
100	3	6	5	6	7	7
101	3	6	6	5	5	6
102	3	5	6	6	6	6
103	3	6	6	7	6	7
104	3	5	5	6	5	6
105	3	6	6	5	6	7
106	2	7	6	7	7	6
107	3	6	5	5	5	5
108	3	6	6	6	6	6
109	3	5	6	6	5	9
110	3	5	6	5	5	6
111	3	6	5	5	5	5
112	3	6	6	7	7	7
113	2	6	6	5	5	7
Mean		5.7	5.7	6.0	5.8	6.4
SD		0.4	0.4	0.7	0.7	1.0
N		14	14	14	14	14
%Diff		3.7	9.3	6.8	6.0	6.7

Appendix 8

Individual food consumption: pretreatment and dosing period

513351

Key Page

Cage Contents

Cage Number	Animal Numbers	Cage Number	Animal Numbers
1	1001	2	1002
3	1003	4	1004
5	1005	6	1006
7	1007	8	1008
9	1009	10	1010
11	1011	12	1012
13	1013	14	1014
15	1015	16	1016
17	1017	18	1018
19	1019	20	1020
21	1101	22	1102
23	1103	24	1104
25	1105	26	1106
27	1107	28	1108
29	1109	30	1110
31	1111	32	1112
33	1113	34	1114
35	1115	36	1116
37	1117	38	1118
39	1119	40	1120
41	2001	42	2002
43	2003	44	2004
45	2005	46	2006
47	2007	48	2008
49	2009	50	2010
51	2011	52	2012

Appendix 8

Individual food consumption: pretreatment and dosing period

513351

Key Page

Cage Contents (Continued)

Cage Number	Animal Numbers	Cage Number	Animal Numbers
53	2013	54	2014
55	2015	56	2016
57	2017	58	2018
59	2019	60	2020
61	2101	62	2102
63	2103	64	2104
65	2105	66	2106
67	2107	68	2108
69	2109	70	2110
71	2111	72	2112
73	2113	74	2114
75	2115	76	2116
77	2117	78	2118
79	2119	80	2120
86	1501, 1502, 1503	87	1504, 1505, 1506
88	1507, 1508, 1509	89	1510, 1511, 1512
90	1513, 1514, 1515	91	1516, 1517, 1518
92	1519, 1520	93	1601, 1602, 1603
94	1604, 1605, 1606	95	1607, 1608, 1609
96	1610, 1611, 1612	97	1613, 1614, 1615
98	1616, 1617, [1618]	99	1619, 1620
100	2501, 2502, 2503	101	2504, 2505, 2506
102	2507, 2508, 2509	103	2510, 2511, 2512
104	2513, 2514, 2515	105	2516, 2517, 2518
106	2519, 2520	107	2601, 2602, 2603
108	2604, 2605, 2606	109	2607, 2608, 2609

Appendix 8

Individual food consumption: pretreatment and dosing period

513351

Key Page

Cage Contents (Continued)

Cage Number	Animal Numbers	Cage Number	Animal Numbers
110	2610, 2611, 2612	111	2613, 2614, 2615
112	2616, 2617, 2618	113	2619, 2620

[] = Animal exited cage during results period;

Measurement Descriptions

Headings Used	Description
Daily Food Cons Per Animal	Mean Daily Food Cons. Per Animal

Measurement/Statistics

Measurement	Descriptive
Daily Food Cons Per Animal	Mean
	Standard Deviation
	Count
	% Difference from Control

Group Information

Short Name	Long Name	Type	Report Headings 1-4		
1	1	Control	70	ul	Group 1
2	2	Dose	70	ul	Group 2

Appendix 8

Individual food consumption: pretreatment and dosing period

513351

Key Page

Comment Abbreviations
RC = Result Comment

Appendix 8

Individual food consumption: recovery period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
21	1	7	6	6	6	6	6	6
22	1	6	6	6	5	7	5	6
23	1	5	6	5	5	5	5	5
24	1	8	8	8	8	8	7	8
25	1	6	5	5	5	6	5	6
26	1	7	6	7	6	7	1	7
27	1	7	7	7	7	8	6	7
28	1	6	6	6	6	6	6	6
29	1	6	6	6	6	6	6	6
30	1	7	7	7	7	8	7	7
31	1	6	6	6	6	7	8	7
32	1	7	7	6	8	8	8	7
33	1	7	6	7	6	7	7	6
34	1	6	6	6	7	6	7	6
35	1	7	7	9	9	9	12	9
36	1	7	7	7	7	10	7	7
37	1	6	6	7	7	7	7	6
38	1	6	6	6	6	6	7	6
39	1	7	6	7	7	7	7	7

Appendix 8

Individual food consumption: recovery period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
40	1	8	6	8	7	8	8	7
	Mean	6.6	6.1	6.6	6.5	7.1	6.5	6.5
	SD	0.7	0.5	1.0	1.0	1.2	1.8	0.9
	N	20	20	20	20	20	20	20

Appendix 8

Individual food consumption: recovery period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
61	1	6	6	5	6	6	8	6
62	1	6	5	5	6	6	6	5
63	1	10	9	10	10	8	9	8
64	1	7	6	6	6	5	7	6
65	1	6	6	6	7	6	7	6
66	1	6	6	7	7	6	8	6
67	1	5	5	6	5	6	5	6
68	1	7	7	6	7	6	7	7
69	1	7	6	6	7	6	8	6
70	1	7	9	8	9	8	9	7
71	1	8	7	6	7	7	7	6
72	1	7	7	7	7	7	8	7
73	1	6	7	7	7	6	7	7
74	1	7	7	8	8	8	8	8
75	1	5	6	5	6	6	6	6
76	1	6	5	6	6	6	6	6
77	1	6	6	6	7	8	8	7
78	1	7	7	6	7	7	8	7
79	1	5	6	5	5	5	6	6

Appendix 8

Individual food consumption: recovery period

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
80	1	9	9	8	9	9	10	9
	Mean	6.6	6.6	6.5	6.9	6.5	7.2	6.6
	SD	1.2	1.2	1.3	1.2	1.1	1.2	1.0
	N	20	20	20	20	20	20	20
	%Diff	-0.8	8.0	-1.0	5.2	-7.3	10.6	0.3

Appendix 8

Individual food consumption: recovery period

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 1	No. in Cage	Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
93	3	6	6	5	5	5	6	5
94	3	5	5	6	5	5	6	5
95	3	6	6	6	6	7	6	6
96	3	6	6	5	5	6	7	6
97	3	6	5	7	7	8	6	7
98	2	6	6	5	6	5	6	7
99	2	5	6	6	5	5	6	5
	Mean	5.7	5.5	5.6	5.6	5.8	6.1	5.9
	SD	0.6	0.4	0.6	0.5	1.3	0.5	0.6
	N	7	7	7	7	7	7	7

Appendix 8

Individual food consumption: recovery period

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		50 → 53	53 → 57	57 → 60	60 → 64	64 → 67	67 → 71	71 → 74
107	3	6	6	6	6	6	6	6
108	3	6	6	6	6	6	6	6
109	3	5	6	6	5	6	7	5
110	3	6	6	5	6	6	6	6
111	3	6	6	5	6	6	6	5
112	3	7	6	7	7	6	6	6
113	2	5	5	6	6	6	5	6
	Mean	5.8	5.7	5.7	6.0	5.9	6.0	5.7
	SD	0.7	0.2	0.6	0.5	0.3	0.6	0.4
	N	7	7	7	7	7	7	7
	%Diff	2.0	5.0	1.4	8.1	1.2	-2.0	-3.2

Appendix 8

Individual food consumption: immunogenicity animals

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
81	1	6	8	7	6	7	7	5
82	1	7	5	9	7	8	7	7
83	1	6	5	7	6	6	6	7
84	1	6	5	7	7	7	7	5
85	1	6	5	7	7	7	7	5
	Mean	6.1	5.6	7.2	6.5	6.9	6.5	5.8
	SD	0.3	1.3	1.2	0.6	0.5	0.6	1.1
	N	5	5	5	5	5	5	5

Appendix 8

Individual food consumption: immunogenicity animals

513351
Sex: Male Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
81	1	7	7	7	7	6
82	1	7	8	7	7	7
83	1	6	7	6	5	7
84	1	7	7	6	7	6
85	1	6	6	6	7	5
	Mean	6.5	6.7	6.5	6.4	6.2
	SD	0.4	0.6	0.6	0.7	0.8
	N	5	5	5	5	5

Appendix 8

Individual food consumption: immunogenicity animals

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date						
		-7 → 1	1 → 2	8 → 11	11 → 15	15 → 18	18 → 22	22 → 23
114	3	5	4	6	6	6	6	6
115	2	5	3	5	5	5	5	4
	Mean	4.8	3.3	5.5	5.3	5.6	5.5	4.8
	SD	0.1	1.1	0.2	0.3	0.7	0.5	1.2
	N	2	2	2	2	2	2	2

Appendix 8

Individual food consumption: immunogenicity animals

513351
Sex: Female Daily Food Cons Per Animal (g)

70 ul Group 2	No. in Cage	Day(s) Relative to Animal Start Date				
		29 → 32	32 → 36	36 → 39	39 → 43	43 → 44
114	3	5	6	5	5	6
115	2	5	6	5	5	5
	Mean	5.1	5.7	5.3	5.0	5.3
	SD	0.5	0.1	0.1	0.3	0.5
	N	2	2	2	2	2

Appendix 8

Individual food consumption: immunogenicity animals

513351

Key Page

Cage Contents

Cage Number	Animal Numbers	Cage Number	Animal Numbers
81	2201	82	2202
83	2203	84	2204
85	2205	114	2701, 2702, 2703
115	2704, 2705		

Measurement Descriptions

Headings Used	Description
Daily Food Cons Per Animal	Mean Daily Food Cons. Per Animal

Measurement/Statistics

Measurement	Descriptive
Daily Food Cons Per Animal	Mean
	Standard Deviation
	Count

Group Information

Short Name	Long Name	Type	Report Headings 1-4		
2	2	Dose	70	ul	Group 2

Appendix 9

Individual dermal observations

Explanation page

Abbreviation	Description	Abbreviation	Description
PR	Pre-dose	4H	4 hours post-dose
HUS1	Observation following dosing		

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

Only animals with clinical observations on at least one occasion are presented in this appendix.

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 9

Individual dermal observations

513351

70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1001	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1002	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1003	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1004	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1005	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1006	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1007	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1008	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1009	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1010	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1011	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1012	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1013	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1014	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1015	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1016	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1017	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1018	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1019	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1020	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1101	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1102	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1103	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1104	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1105	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1106	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1107	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1108	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1109	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1110	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1111	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1112	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1113	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1114	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1115	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1116	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1117	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1118	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1119	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1120	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1001	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1002	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1003	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1004	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1005	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1006	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1007	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1008	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1009	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1010	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1011	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1012	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1013	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1014	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1015	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1016	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1017	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1018	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1019	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1020	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1101	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1102	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1103	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1104	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1105	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1106	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1107	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1108	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1109	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1110	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1111	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1112	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1113	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1114	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1115	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1116	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1117	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1118	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1119	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1120	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2001	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2002	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2003	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2004	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	.	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	.	.	.	.	.	.
2005	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2006	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2007	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2008	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2009	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2010	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2011	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2012	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2012	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2013	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2014	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2015	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2016	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2017	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2018	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2019	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2020	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2101	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2102	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2103	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2104	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2104	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2105	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2106	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2107	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2108	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2109	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2110	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2111	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2112	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2113	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2114	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2115	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2116	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2116	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2117	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2118	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2119	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2120	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2201	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2202	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2203	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2204	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2205	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2001	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2002	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2003	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2004	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	.	.					
2005	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2006	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2007	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2008	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2009	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2010	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2011	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2012	Edema, Hindlimb, Left, Grade 0	X	.					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2012	Erythema, Hindlimb, Left, Grade 0	X	.					
2013	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2014	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2015	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2016	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2017	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2018	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2019	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2020	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2101	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2102	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2103	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2104	Edema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2104	Erythema, Hindlimb, Left, Grade 0	.	X					
2105	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2106	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2107	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2108	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2109	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2110	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2111	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2112	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2113	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2114	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2115	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2116	Edema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2116	Erythema, Hindlimb, Left, Grade 0	.	X					
2117	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2118	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2119	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2120	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2201	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2202	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2203	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2204	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2205	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1501	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1502	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1503	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1504	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1505	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1506	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1507	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1508	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1509	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1510	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1511	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1512	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1513	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1514	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1515	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1516	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1517	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1518	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1519	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1520	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1601	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1602	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1603	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1604	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1605	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1606	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1607	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1608	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1609	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1610	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1611	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1612	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1613	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1614	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1615	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1616	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1617	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1618	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	.	.
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	.	.
1619	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
1620	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1501	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1502	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1503	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1504	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1505	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1506	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1507	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1508	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1509	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1510	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1511	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1512	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1513	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1514	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1515	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1516	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1517	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1518	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1519	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1520	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
1601	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1602	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1603	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1604	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1605	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1606	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1607	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1608	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1609	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1610	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1611	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1612	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1613	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1614	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1615	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1616	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1617	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1618	Edema, Hindlimb, Left, Grade 0	.	.					
	Erythema, Hindlimb, Left, Grade 0	.	.					
1619	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
1620	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2501	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2502	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2503	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2504	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2505	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2506	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2507	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2508	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2509	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2510	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2511	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2512	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2513	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2514	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2515	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2516	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2517	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2518	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2519	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2520	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2601	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2602	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2603	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2604	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2605	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2606	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2607	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2608	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2609	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2610	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2611	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2612	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2613	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2614	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2615	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2616	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2617	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2618	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2619	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2620	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2701	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2702	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2703	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2704	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
2705	Edema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Left, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2501	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2502	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2503	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2504	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2505	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2506	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2507	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2508	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2509	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2510	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2511	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2512	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2513	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2514	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2515	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2516	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2517	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2518	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2519	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2520	Edema, Hindlimb, Left, Grade 0	X	.					
	Erythema, Hindlimb, Left, Grade 0	X	.					
2601	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2602	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2603	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2604	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2605	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2606	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2607	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2608	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2609	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2610	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2611	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2612	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2613	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2614	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2615	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2616	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 1	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2617	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2618	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2619	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2620	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2701	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2702	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2703	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2704	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					
2705	Edema, Hindlimb, Left, Grade 0	.	X					
	Erythema, Hindlimb, Left, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1001	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1002	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1003	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1004	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1005	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1006	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1007	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1008	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1009	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1010	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1011	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1012	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1013	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1014	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1015	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1016	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1017	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1018	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1019	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1020	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1101	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1102	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1103	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1104	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1105	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1106	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1107	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1108	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1109	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1110	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1111	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1112	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1113	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1114	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1115	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1116	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1117	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1118	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1119	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1120	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1001	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1002	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1003	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1004	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1005	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1006	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1007	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1008	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1009	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1010	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1011	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1012	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1013	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1014	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1015	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1016	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1017	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1018	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1019	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1020	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1101	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1102	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1103	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1104	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1105	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1106	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1107	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1108	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1109	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1110	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1111	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1112	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1113	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1114	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1115	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1116	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1117	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1118	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1119	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1120	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2001	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2002	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2003	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2004	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2005	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2006	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2007	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2008	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2009	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2010	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2011	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2012	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2013	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2014	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2015	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2016	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2017	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2018	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2019	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2020	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2101	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2102	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2103	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2104	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2105	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2106	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2107	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2108	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2109	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2110	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2111	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2112	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2113	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2114	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2115	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2116	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2117	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2118	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2119	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2120	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2201	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2202	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2203	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2204	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2205	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2001	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2002	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2003	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2004	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2005	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2006	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2007	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2008	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2009	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2010	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2011	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2012	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2013	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2014	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2015	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2016	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2017	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2018	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2019	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2020	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2101	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2102	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2103	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2104	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2105	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2106	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2107	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2108	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2109	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2110	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2111	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2112	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2113	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2114	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2115	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2116	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Male	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2117	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2118	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2119	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2120	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2201	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2202	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2203	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2204	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2205	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1501	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1502	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1503	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1504	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1505	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1506	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1507	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1508	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1509	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1510	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1511	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1512	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1513	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1514	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1515	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1516	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1517	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1518	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1519	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1520	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1601	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1602	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1603	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1604	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1605	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1606	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1607	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1608	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1609	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1610	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1611	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1612	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1613	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1614	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1615	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1616	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
1617	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1618	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	.	.
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	.	.
1619	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
1620	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1501	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1502	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1503	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1504	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1505	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1506	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1507	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1508	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1509	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1510	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1511	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1512	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1513	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1514	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1515	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1516	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1517	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1518	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1519	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1520	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
1601	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1602	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1603	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1604	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1605	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1606	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1607	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1608	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1609	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1610	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1611	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1612	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1613	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1614	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1615	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1616	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 1 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
1617	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1618	Edema, Hindlimb, Right, Grade 0	.	.					
	Erythema, Hindlimb, Right, Grade 0	.	.					
1619	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
1620	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2501	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2502	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2503	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2504	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2505	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2506	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2507	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2508	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2509	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2510	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2511	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2512	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2513	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2514	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2515	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2516	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2517	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2518	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2519	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2520	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2601	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2602	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2603	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2604	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

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Individual dermal observations

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70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2605	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2606	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2607	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2608	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2609	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2610	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2611	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2612	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2613	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2614	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2615	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2616	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		1 Pre	1 4H	22 Pre	22 4H	23 HUS1	43 Pre	43 4H
2617	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2618	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2619	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2620	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2701	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2702	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2703	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2704	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
2705	Edema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X
	Erythema, Hindlimb, Right, Grade 0	X	X	X	X	X	X	X

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2501	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2502	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2503	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2504	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2505	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2506	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2507	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2508	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2509	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2510	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2511	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2512	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2513	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2514	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2515	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2516	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2517	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2518	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2519	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2520	Edema, Hindlimb, Right, Grade 0	X	.					
	Erythema, Hindlimb, Right, Grade 0	X	.					
2601	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2602	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2603	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2604	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2605	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2606	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2607	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2608	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2609	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2610	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2611	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2612	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2613	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2614	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2615	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2616	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

Appendix 9

Individual dermal observations

513351

70 ul Group 2 Sex: Female	Observation Type: Local Irritation Assess 2	Day(s) Relative to Start Date						
		45 HUS1	74 HUS1					
2617	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2618	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2619	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2620	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2701	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2702	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2703	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2704	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					
2705	Edema, Hindlimb, Right, Grade 0	.	X					
	Erythema, Hindlimb, Right, Grade 0	.	X					

X=Present

Appendix 10

AZD1222
513351 (1156PM)

Charles River Laboratories

Irwin Measurements Phase Report	
Project name	AZD1222
Study number	513351
AstraZeneca reference no	1156PM
GLP compliance	Yes
Version ID	Final
Date approved	04 December 2020

AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery
Irwin Measurements Phase Report

This document contains trade secrets and confidential commercial information, disclosure of which is prohibited without providing advance notice to AstraZeneca and opportunity to object.

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1. INTRODUCTION

AZD1222 (ChAdOx1-nCovd-19) is under development by AstraZeneca as a potential COVID-19 disease prevention vaccine. AZD1222 is a recombinant replication-defective chimpanzee adenovirus expressing the SARS-CoV-2 Spike (S) surface glycoprotein. The objective of this study phase was to evaluate the potential effects of AZD1222 in the Irwin Screen, a behavioural, neurological and overt toxicity scoring protocol designed to detect a wide range of adverse effects.

2. EXPERIMENTAL DATES

Irwin measurement data analysis and interpretation work started:	28 October 2020
Irwin measurement data analysis and interpretation work completed:	25 November 2020

3. STUDY DESIGN

Details of groups, dose levels and numbers of animals used are given in Table 1 and Table 2.

The test or control item was administered to the appropriate animals by intramuscular injection (dose split across two dose sites) on Days 1, 22 and 43. The first day of dosing was designated as Day 1.

Table 1 Dose groups

Group No.	Animal Numbers					
	Main Study		Recovery		Immunogenicity	
	Males	Females	Males	Females	Males	Females
1	1001-1020	1501-1520	1101-1120	1601-1620	-	-
2	2001-2020	2501-2520	2101-2120	2601-2620	2201-2205	2701-2705

- = Not applicable

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Table 2 Dose levels

Group No.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	$3.7x10^{10}$	$5.3 x10^{11}$

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 70µL)

* Control (vehicle); 10 mM histidine, 7.5% (v/w) sucrose, 35 mM sodium chloride, 1 mM magnesium chloride, 0.1% (v/w) polysorbate-80, 0.1 mM EDTA and 0.5% (v/w) ethanol, pH 6.6

4. MATERIALS AND METHODS

4.1 Irwin screen observations

On Days 8 and 29, the first six males per group (main study animals) were observed in the morning and the following parameters were included in the observations:

Occurrence of vocalisation, stereotypies, aggressiveness, abnormal gait, straub tail, abducted hind limbs, tremor, twitches, convulsions, body posture, sedation, catalepsy, ptosis, exophthalmos, salivation, lacrimation, piloerection, abnormal respiration, defecation, urination and death.

Increase or decrease of spontaneous activity, touch response and body tonus. Increase of sniffing, grooming, scratching and rearing.

Decreased pinna reflex, traction response and grip strength.

Frequencies of animals exhibiting symptoms were recorded. Symptoms were scored from 0 to 3, where 0 represented no findings and 3 the highest score.

Pupil size was measured using a guidance chart to estimate the size in millimetres.

Body temperature was measured by using a probe inserted approximately 2 cm past the anal sphincter. At least 30 minutes prior to the commencement of observations, to reduce measurement variability, a temperature habituation trial was conducted by inserting the temperature probe, however, no temperature data was collected during this trial.

4.1.1 Apparatus

The traction response was measured by assessing the ability of mice to pull themselves up onto a cage top.

Grip strength was assessed by allowing mice to grip onto the cage lid. The mouse was held and allowed to grip onto the grid with all paws and then gently pulled backwards from the lid.

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A proforma with a size scale was used for assessing relative pupil sizes only and no exact sizes were calculated or implied.

A thermometer, with a flexible probe, was used to measure body temperature.

4.1.2 Irwin data analysis

Statistical analysis results are presented in Table 4 and Table 5.

Qualitative data
Frequencies of mice exhibiting a given symptom are reported in tabulated form. Severity scores of the observed symptoms were measured in four categories (0, 1, 2, or 3) and are presented as the dose group mean of the maximal possible score [MPS=score/max score*100] for each mouse at each time point.

As there were no positive findings noted on this study (each observation scored 0), it was not possible to run a Fisher's exact test, therefore no statistical analysis was performed on the qualitative data.

Quantitative data
All statistical tests were two-sided and performed at the 5% significance level. Where data were collected at repeated time points, each time point was analysed separately.

Pairwise comparisons were performed against the control group (Group 1). The following pairwise comparisons were performed:

Control Group v Group 2

Pupil size and body temperature was analysed using a parametric ANOVA. Pairwise comparisons were made using a Dunnett's test (equivalent to t-test in Nevis 2012 tables).

In the ANOVA summary tables, the results of the analysis have been reported indicating the level of statistical significance ($p \leq 0.05$, $p \leq 0.01$ and $p \leq 0.001$) of each pairwise comparison.

Actual p-values are not reported in the summary tables for these analyses.

4.2 Computerised systems

Table 3 Critical computerised systems

System Name	Version	Description of data collected and/or analysed
In-house reporting software Nevis (using SAS)	9.4	Applicable in-life
Share Document Management System	1.0	Reporting
DocuSign	19	Collection of CFR Part 11 compliant signature

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5. DEVIATIONS AND OTHER EVENTS

In error, the protocol omitted the body temperature data from statistical analysis for the Irwin Screen phase of the study. Data was scheduled to be collected, with the intention to analyse the data as is standard on this data type. As intention of the study was carried out as planned, this deviation is deemed to have had no impact on the integrity or outcome of the study.

6. RESULTS AND DISCUSSIONS

Mean data and statistical analysis of Irwin measurements data are presented in Table 4 and Table 5. Individual animal results are presented in Appendix 1 to Appendix 3.

No effect on body temperature, pupil size or any of the Irwin Screen observations were noted following administration of AZD1222.

7. CONCLUSION

The effects of AZD1222 on autonomic, neuromuscular, sensorimotor, behavioural parameters and effects on body temperature and pupil size were assessed in an Irwin Screen in conscious male mice in the morning on Day 8 and Day 29 of the 6 week intermittent dosing intramuscular vaccine toxicity study, during which male and female CD-1 mice received doses of 0 (control) or an AZD1222 viral particle dose of $3.7x10^{10}$ on Days 1, 22 and 43.

Following intramuscular administration of AZD1222 at a viral particle dose of $3.7x10^{10}$, there were no effects on body temperature, pupil size or Irwin Screen observations.

The No Observed Effect Level (NOEL) for the Irwin Screen observations, body temperature and pupil size was a viral particle dose of $3.7x10^{10}$.

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8. REPORT APPROVAL

This report represents a true and accurate record of the results obtained.

Individual Scientist

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UK

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Table 4
Summary of body temperatures (°C)

Group / Sex		Day 8	Day 29
1M	Mean	37.9	37.6
	N	6	6
	SE	0.2	0.3
2M	Mean	38.3	38.2
	N	6	6
	SE	0.2	0.3

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Charles River Laboratories

Table 5
Summary of pupil size (mm)

Group / Sex		Day 8	Day 29
1M	Mean	0.5	0.5
	N	6	6
	SE	0.0	0.0
2M	Mean	0.5	0.5
	N	6	6
	SE	0.0	0.0

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Appendix 1
Individual body temperature (°C)

Group / Sex	Animal No.	Day 8	Day 29
1M	1001	37.6	36.6
	1002	37.6	38.8
	1003	38.8	37.9
	1004	38.2	37.7
	1005	37.7	37.7
	1006	37.6	37.1
2M	2001	37.7	37.3
	2002	38.5	38.5
	2003	38.7	39.1
	2004	38.8	38.5
	2005	37.7	37.7
	2006	38.4	37.8

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Charles River Laboratories

Appendix 2
Individual pupil size (mm)

Group / Sex	Animal No.	Day 8	Day 29
1M	1001	0.5	0.5
	1002	0.5	0.5
	1003	0.5	0.5
	1004	0.5	0.5
	1005	0.5	0.5
	1006	0.5	0.5
2M	2001	0.5	0.5
	2002	0.5	0.5
	2003	0.5	0.5
	2004	0.5	0.5
	2005	0.5	0.5
	2006	0.5	0.5

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Abnormal defecation

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Abnormal gait

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Abnormal respiration

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Abnormal urination

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Aggressiveness

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Body posture

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Body tonus decreased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Body tonus increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Catalepsy

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Convulsions

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Death

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Exophthalmos

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Grip strength decreased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Grooming increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Lacrimation

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Piloerection

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Pinna reflex decreased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Ptosis

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Rearing increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Salivation

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Scratching increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Sedation

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Sniffing increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Spontaneous activity decreased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Spontaneous activity increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Stereotypies

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Straub tail

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Touch response decreased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Touch response increased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Traction response decreased

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Appendix 3

Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Tremor

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Twitches

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Vocalization

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

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Irwin scores in Male CD-1 Mice, frequency and % of maximum possible score (%MPS)

Abducted hindlimb

Dose Group	Animal No	Day 8	Day 29
1	1001	0	0
	1002	0	0
	1003	0	0
	1004	0	0
	1005	0	0
	1006	0	0
2	2001	0	0
	2002	0	0
	2003	0	0
	2004	0	0
	2005	0	0
	2006	0	0

Group 1	Number of positive findings	0	0
Group 2	Number of positive findings	0	0

Group 1	% Maximum Possible Score	0	0
Group 2	% Maximum Possible Score	0	0

Appendix 11

Individual haematology values

Explanation pages

ADVIA 2120i Analyser

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Red Blood Cell Distribution Width	RDW	%	Calculated
Red Blood Cell Distribution Width Gated (Wistar Rat)	RDWG	%	Calculated
Haematocrit	HCT	L/L	Calculated
Haemoglobin	HGB	g/dL	Colorimetric
Haemoglobin	HGB	g/L	Colorimetric
Mean Corpuscular Haemoglobin	MCH	pg	Calculated
Mean Corpuscular Haemoglobin Concentration	MCHC	g/dL	Calculated
Mean Corpuscular Haemoglobin Concentration	MCHC	g/L	Calculated
Mean Corpuscular Volume	MCV	fL	Calculated
Mean Platelet Volume	MPV	fL	Calculated
Platelet Count	PLT	$x10^9/L$	Light scatter
Red Blood Cell Count	RBC	$x10^{12}/L$	Light scatter
Reticulocytes	RETIC	$x10^9/L$	Calculated
Reticulocytes Percent	RETIC	%	Light scatter
White Blood Cell Count	WBC	$x10^9/L$	Light scatter
White Blood Cell Differential Count			
Neutrophils Percent	NEUT	%	Light scatter
Lymphocytes Percent	LYMPH	%	Light scatter
Monocytes Percent	MONO	%	Light scatter
Eosinophils Percent	EOS	%	Light scatter
Basophils Percent	BASO	%	Light scatter
Large Unstained Cells Percent	LUC	%	Light scatter
Neutrophils	NEUT	$x10^9/L$	Calculated
Lymphocytes	LYMPH	$x10^9/L$	Calculated
Monocytes	MONO	$x10^9/L$	Calculated
Eosinophils	EOS	$x10^9/L$	Calculated
Basophils	BASO	$x10^9/L$	Calculated
Large Unstained Cells	LUC	$x10^9/L$	Calculated
Myeloperoxidase Index	MPXI	%	Calculated staining intensity of Neutrophils relative to the archetype.
Corpuscular Hemoglobin Concentration Mean	CHCM	g/dL	Calculated
Corpuscular Hemoglobin Concentration Mean	CHCM	g/L	Calculated
Platelet Component Distribution Width	PCDW	g/dL	Calculated
Platelet Component Distribution Width	PCDW	g/L	Calculated
PCT	PCT	%	Calculated
PCT	PCT	L/L	Calculated
Platelet Distribution Width	PDW	%	Calculated
Mean Platelet Component	MPC	g/dL	Calculated
Mean Platelet Component	MPC	g/L	Calculated
Hemoglobin Concentration Distribution Width	HDW	g/dL	Calculated

Appendix 11

ADVIA 2120i Analyser

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Hemoglobin Concentration Distribution Width	HDW	g/L	Calculated
Erythrocyte Sedimentation Rate	ESR	mm/h	Modified Westergren method
Bronchoalveolar Lavage Total Red Blood Cell	BAL RBC	Total Cells x 10^6	Light scatter
Bronchoalveolar Lavage Total White Blood Cell	BAL WBC	Total Cells x 10^6	Light scatter
Bronchoalveolar Lavage Total Neutrophil	BAL NEUT	Total Cells x 10^6	Light scatter
Bronchoalveolar Lavage Total Macrophage	BAL MACRO	Total Cells x 10^6	Light scatter
Bronchoalveolar Lavage Total Eosinophil	BAL EOS	Total Cells x 10^6	Light scatter
Bronchoalveolar Lavage Total Lymphocyte	BAL LYMPH	Total Cells x 10^6	Light scatter
Bronchoalveolar Lavage Total Basophil	BAL BASO	Total Cells x 10^6	Light scatter

Siemens HEMA-TEK 2000 / 3000 Automated Slide Stainer

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Blood Smear Stain		None	Modified Wright Stain

Manual and visual

Analysed parameter descriptions

Parameter	Abbreviation
- Red Blood Cell Morphology	RBC MORPH
- White Blood Cell Morphology	WBC MORPH
- Platelet Morphology	PLT MORPH

Cell morphology parameters

Units: 1+ (Minimal), 2+ (Mild), 3+ (Moderate), 4+ (Marked)

	Abbreviation	Units	Methodology
- Cytoplasmic Basophilia Neutrophil	CYTO BASO NEUT	1+, 2+, 3+, 4+	Microscopic Examination
- Polychromasia	POLY	1+, 2+, 3+, 4+	Microscopic Examination
- Anisocytosis	ANISO	1+, 2+, 3+, 4+	Microscopic Examination
- Hypochromasia	HYPOCHROMIA	1+, 2+, 3+, 4+	Microscopic Examination
- Reactive Lymphocytes	REACTIVE LYMPH	1+, 2+, 3+, 4+	Microscopic Examination
- Megakaryocytes	MEGAK	1+, 2+, 3+, 4+	Microscopic Examination
- Smudge Cells	SMUDGE CELL	1+, 2+, 3+, 4+	Microscopic Examination
- Microcytes	MICROCYTES	1+, 2+, 3+, 4+	Microscopic Examination

Appendix 11

Cell morphology parameters
Units: 1+ (Minimal), 2+ (Mild), 3+ (Moderate), 4+ (Marked)

	Abbreviation	Units	Methodology
- Macrocytes	MACROCYTES	1+, 2+, 3+, 4+	Microscopic Examination
- Poikilocytosis	POIK	1+, 2+, 3+, 4+	Microscopic Examination
- Rouleaux Formation	ROULEAUX	1+, 2+, 3+, 4+	Microscopic Examination
- Agglutination	AGGL	1+, 2+, 3+, 4+	Microscopic Examination
- Red Blood Cell Clumping	RBC Clumping	1+, 2+, 3+, 4+	Microscopic Examination
- Acanthocytes	ACAN	1+, 2+, 3+, 4+	Microscopic Examination
- Codocytes	TARGET CELLS	1+, 2+, 3+, 4+	Microscopic Examination
- Dacryocytes	DACR	1+, 2+, 3+, 4+	Microscopic Examination
- Platelet Clumps	PLATELET CLUMPS	1+, 2+, 3+, 4+	Microscopic Examination
- Eccentrocytes	ECCENTCY	1+, 2+, 3+, 4+	Microscopic Examination
- Schistocytes	SCHZ	1+, 2+, 3+, 4+	Microscopic Examination
- Spherocytes	SPHR	1+, 2+, 3+, 4+	Microscopic Examination
- Stomatocytes	STOM	1+, 2+, 3+, 4+	Microscopic Examination
- Howell Jolly Bodies	HJB	1+, 2+, 3+, 4+	Microscopic Examination
- Basophilic Stippling	BASO STIP RBC	1+, 2+, 3+, 4+	Microscopic Examination
- Echinocytes	ECHINO	1+, 2+, 3+, 4+	Microscopic Examination
- Vacuolated Neutrophils	NEUTVAC	1+, 2+, 3+, 4+	Microscopic Examination
- Vacuolated Lymphocytes	LYMVAC	1+, 2+, 3+, 4+	Microscopic Examination
- Döhle Bodies	DOHLE BODY	1+, 2+, 3+, 4+	Microscopic Examination
- Degenerated Cells	DEG CELL	1+, 2+, 3+, 4+	Microscopic Examination
- Ovalocytes	OVAL	1+, 2+, 3+, 4+	Microscopic Examination
- Large Platelets Alpha	LARGE PLATELETS	1+, 2+, 3+, 4+	Microscopic Examination
- Immature Neutrophils Morphology	IMM NEUT MORPH	1+, 2+, 3+, 4+	Microscopic Examination
- Heinz Bodies	HEINZ BODY	1+, 2+, 3+, 4+	Microscopic Examination
- Plasmodium	PLASMOD	1+, 2+, 3+, 4+	Microscopic Examination
- Kurloff Cell	KURL	1+, 2+, 3+, 4+	Microscopic Examination
- Burr Cells	BURR	1+, 2+, 3+, 4+	Microscopic Examination
- Neutrophils Band Form Morphology	NEUT BAND MORPH	1+, 2+, 3+, 4+	Microscopic Examination
- Nuclear Swelling	NUC SWELL NEUT	1+, 2+, 3+, 4+	Microscopic Examination
- Toxic Granulation	TOXG	1+, 2+, 3+, 4+	Microscopic Examination
- Immature Cells	IMM CELL	10^9/L	Microscopic Examination

Parameter	Abbreviation	Units	Methodology
Nucleated Red blood Cells/100 Leukocytes	RBCNUCLE	#/100WBC	Microscopic Examination
Heinz Bodies Percent	HEINZ BODY	%	Microscopic examination. Methyl violet in physiological saline
Reticulocyte Percent	RETIC	%	Microscopic enumeration, new methylene blue stain

Appendix 11

Note: This is a comprehensive list of parameters and abbreviations. All of the parameters and abbreviations listed may not be applicable to this report.

Clinical pathology data flags

Abbreviation	Description
-	No sample or no result. The exception is Urine Microscopic, Red and White Blood Cell Morphology and Platelet Morphology where it denotes an abnormal finding in one or more parameter
ADQ	Adequate
AVS	Suspected aberrant value
BE0	Volume below 0.1mL
CLOT	Sample clotted
COM	Contaminated with organic material
COME	See comment value excluded
COMI	See comment value included
COMM	Comment added
DEC	Decreased
Exc	Exclude
GFC	Gross fecal contamination present
INC	Increased
INV	Invalid result
IRPS	Presence of abundant plasmodium species
ISH	Result invalid due to severe haemolysis
ISL	Result invalid due to severe lipaemia
L100	Less than 100 cells used to perform differential
LLOQ	Less than lower limit of quantification
MDIFF	Manual differential
NA	Not applicable
NAF	No abnormal findings
NC	Not calculable
NCD	No clot detected
NRBC	WBC corrected for presence of nucleated RBC
NSCH	Not scheduled to be performed
NT	Not taken
OA	Omitted activity
OOS	Sample analysed outside of established stability, results for information only
QNS	Quantity not sufficient
RSV	Refer to source values
S	Spillage
SAMU	Large number of smudge cells
SNC	Sample not collected
SNR	Sample not received
SVGS	Sample volume greater than specified
SVLS	Sample volume less than specified
TERR	Technical error (explanation required)
TNP	Test not performed
TNR	Test not reported
UNCR	Results are not reproducible
UNEX	Unscheduled data excluded from statistics

Appendix 11

Clinical pathology data flags

Abbreviation	Description
UPTD	Unable to perform due to technical difficulty
UTC	Unable to collect
UTD	Unable to determine
UTDH	Unable to determine due to marked haemolysis
UTDL	Unable to determine due to marked lipaemia
UTDM	Unable to determine results, not confirmed by microscopy
UTDR	Unable to determine results not reproducible
VARR	Assigned value above reportable range
VBRR	Assigned value below reportable range
VNC	Value not calculable
X	Excluded from mean

Note: This is a comprehensive list of clinical pathology data flags. All of the data flags listed may not be applicable to this report.

Appendix 11

Individual haematology values: main study animals

513351

Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
1001	45	3.81	0.55	3.01	0.10	0.13	0.00
1002	45	1.69	0.43	1.13	0.02	0.09	0.01
1003	45	1.28	0.17	1.05	0.02	0.04	0.00
1004	45	4.35	0.70	3.41	0.09	0.09	0.01
1005	45	1.29	0.15	1.06	0.02	0.06	0.00
1006	45	3.54	0.58	2.79	0.12	0.04	0.01
1007	45	3.02	0.64	2.21	0.12	0.04	0.00
1008	45	6.02	1.05	4.69	0.14	0.09	0.01
1009	45	6.24	1.01	4.96	0.15	0.09	0.02
1010	45	7.17	0.75	6.03	0.15	0.16	0.02

Appendix 11

Individual haematology values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
1001	45	0.02	9.86	146	0.463	47.0	14.8
1002	45	0.00	9.64	143	0.465	48.2	14.9
1003	45	0.00	9.76	148	0.480	49.2	15.1
1004	45	0.04	9.69	146	0.465	48.0	15.0
1005	45	0.00	9.76	151	0.482	49.4	15.5
1006	45	0.01	10.60	153	0.486	45.9	14.5
1007	45	0.01	10.40	152	0.482	46.3	14.6
1008	45	0.05	10.66	158	0.489	45.9	14.8
1009	45	0.02	10.38	155	0.482	46.4	14.9
1010	45	0.06	11.23	155	0.496	44.2	13.8

Appendix 11

Individual haematology values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
1001	45	316	12.8	1394	320.8	3.3	-
1002	45	309	14.0	1218	383.6	4.0	1+
1003	45	308	13.0	1196	371.7	3.8	1+
1004	45	313	13.7	1223	264.7	2.7	-
1005	45	313	13.0	1385	291.7	3.0	-
1006	45	315	12.6	1438	289.6	2.7	-
1007	45	316	12.4	1185	296.1	2.8	1+
1008	45	322	12.7	1265	340.1	3.2	-
1009	45	322	12.6	1207	305.6	2.9	-
1010	45	313	12.9	1622	262.8	2.3	-

Appendix 11

Individual haematology values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology			
		ECHINO	PLT MORPH	PLATELET CLUMPS	WBC MORPH
1001	45	-	-	-	-
1002	45	1+	-	2+	NAF
1003	45	3+	-	2+	NAF
1004	45	-	-	-	-
1005	45	-	-	-	-
1006	45	-	-	-	-
1007	45	-	-	2+	NAF
1008	45	-	-	-	-
1009	45	-	-	-	-
1010	45	-	-	-	-

Appendix 11

Individual haematology values: main study animals

513351

Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
2001	45	6.72	0.95	5.45	0.12	0.12	0.01
2002	45	2.35	0.43	1.82	0.03	0.06	0.00
2003	45	1.51	0.25	1.18	0.01	0.05	0.00
2004	45	1.91	0.37	1.46	0.02	0.04	0.01
2005	45	4.07	0.68	3.27	0.03	0.06	0.01
2006	45	3.86	0.85	2.88	0.02	0.07	0.01
2007	45	2.75	0.94	1.69	0.02	0.07	0.00
2008	45	4.40	1.19	3.04	0.04	0.09	0.02
2009	45	1.51	0.31	1.14	0.01	0.03	0.00
2010	45	4.76	0.80	3.70	0.10	0.09	0.01

Appendix 11

Individual haematology values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
2001	45	0.07	10.69	158	0.501	46.9	14.7
2002	45	0.01	10.41	149	0.480	46.1	14.3
2003	45	0.02	9.76	139	0.443	45.3	14.3
2004	45	0.01	10.31	151	0.481	46.7	14.7
2005	45	0.02	9.46	139	0.441	46.6	14.7
2006	45	0.03	10.24	147	0.469	45.8	14.3
2007	45	0.03	10.60	154	0.487	45.9	14.5
2008	45	0.02	9.26	141	0.449	48.4	15.3
2009	45	0.02	9.72	148	0.463	47.6	15.2
2010	45	0.05	10.10	150	0.484	47.9	14.9

Appendix 11

Individual haematology values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
2001	45	314	12.8	1372	341.0	3.2	-
2002	45	311	12.7	1426	366.4	3.5	-
2003	45	315	13.3	1292	306.1	3.1	-
2004	45	314	13.9	1172	283.1	2.7	1+
2005	45	315	12.2	1147	259.6	2.7	1+
2006	45	313	12.4	1246	267.4	2.6	-
2007	45	317	11.7	1241	340.6	3.2	1+
2008	45	315	13.9	999	336.0	3.6	1+
2009	45	320	12.8	1193	287.0	3.0	-
2010	45	310	13.7	1302	319.0	3.2	-

Appendix 11

Individual haematology values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology			
		ECHINO	PLT MORPH	PLATELET CLUMPS	WBC MORPH
2001	45	-	-	-	-
2002	45	-	-	-	-
2003	45	-	-	-	-
2004	45	1+	-	2+	NAF
2005	45	3+	NAF	-	NAF
2006	45	-	-	-	-
2007	45	-	-	2+	NAF
2008	45	-	-	4+	NAF
2009	45	-	-	-	-
2010	45	-	-	-	-

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
1501	45	2.42	0.30	1.96	0.04	0.11	0.00
1502	45	4.20	0.59	3.29	0.13	0.14	0.01
1503	45	2.91	0.57	2.21	0.04	0.07	0.01
1504	45	7.62	0.91	6.37	0.11	0.13	0.03
1505	45	7.81	0.94	6.37	0.15	0.24	0.02
1506	45	6.00	1.21	4.36	0.11	0.29	0.02
1507	45	10.61	2.04	7.92	0.20	0.32	0.03
1508	45	4.64	0.71	3.68	0.13	0.08	0.01
1509	45	3.93	1.11	2.65	0.07	0.08	0.00
1510	45	3.99	0.56	3.24	0.08	0.08	0.01

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
1501	45	0.02	9.10	136	0.434	47.7	15.0
1502	45	0.03	9.84	147	0.475	48.3	14.9
1503	45	0.02	9.97	151	0.473	47.5	15.1
1504	45	0.07	10.57	153	0.484	45.8	14.5
1505	45	0.09	10.30	154	0.484	47.0	14.9
1506	45	0.03	9.73	154	0.480	49.4	15.8
1507	45	0.09	10.04	157	0.490	48.8	15.6
1508	45	0.04	10.88	160	0.503	46.3	14.7
1509	45	0.02	9.42	142	0.436	46.3	15.1
1510	45	0.01	9.18	143	0.446	48.5	15.6

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
1501	45	313	13.4	1003	393.6	4.3	-
1502	45	309	13.2	1125	326.3	3.3	-
1503	45	319	13.5	1170	357.2	3.6	-
1504	45	317	13.1	1207	470.0	4.4	-
1505	45	317	13.0	1265	388.2	3.8	-
1506	45	321	12.2	1161	267.5	2.7	-
1507	45	320	12.7	1161	114.3	1.1	-
1508	45	318	13.2	979	315.7	2.9	-
1509	45	326	13.0	1082	290.3	3.1	-
1510	45	322	12.5	1332	264.4	2.9	-

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology			
		ECHINO	PLT MORPH	PLATELET CLUMPS	WBC MORPH
1501	45	-	-	-	-
1502	45	-	-	-	-
1503	45	-	-	-	-
1504	45	-	-	-	-
1505	45	-	-	-	-
1506	45	-	-	-	-
1507	45	-	-	-	-
1508	45	-	-	-	-
1509	45	-	-	-	-
1510	45	-	-	-	-

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
2501	45	5.22	1.10	3.83	0.04	0.18	0.01
2502	45	5.36	1.55	3.58	0.03	0.12	0.03
2503	45	2.15	0.62	1.40	0.06	0.07	0.00
2504	45	4.60	1.45	2.93	0.03	0.13	0.01
2505	45	6.20	0.96	4.88	0.05	0.18	0.02
2506	45	5.26	0.74	4.26	0.04	0.14	0.02
2507	45	7.29	1.54	5.41	0.04	0.17	0.02
2508	45	3.33	0.92	2.19	0.05	0.10	0.01
2509	45	2.59	0.83	1.64	0.01	0.08	0.00
2510	45	8.46	1.39	6.59	0.06	0.24	0.03

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
2501	45	0.05	9.34	142	0.436	46.7	15.2
2502	45	0.05	9.61	149	0.477	49.6	15.5
2503	45	0.01	10.62	151	0.477	44.9	14.2
2504	45	0.06	9.31	140	0.448	48.2	15.1
2505	45	0.11	9.47	147	0.451	47.6	15.6
2506	45	0.06	10.25	150	0.481	46.9	14.7
2507	45	0.10	9.59	149	0.462	48.1	15.5
2508	45	0.06	9.84	157	0.498	50.6	16.0
2509	45	0.02	10.95	155	0.503	45.9	14.2
2510	45	0.14	9.54	151	0.483	50.6	15.8

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
2501	45	326	13.2	1004	402.0	4.3	-
2502	45	313	13.8	1273	502.2	5.2	1+
2503	45	317	12.9	1152	289.5	2.7	-
2504	45	313	13.2	1074	373.0	4.0	-
2505	45	327	13.8	1120	266.0	2.8	-
2506	45	312	13.3	1212	195.6	1.9	-
2507	45	323	12.6	1253	390.2	4.1	-
2508	45	316	13.4	1055	274.7	2.8	-
2509	45	309	12.5	1194	313.8	2.9	-
2510	45	312	13.5	969	328.3	3.4	-

Appendix 11

Individual haematology values: main study animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology			
		ECHINO	PLT MORPH	PLATELET CLUMPS	WBC MORPH
2501	45	-	-	-	-
2502	45	-	-	2+	NAF
2503	45	-	-	-	-
2504	45	-	-	-	-
2505	45	-	-	-	-
2506	45	-	-	-	-
2507	45	-	-	-	-
2508	45	-	-	-	-
2509	45	-	-	-	-
2510	45	-	-	-	-

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
1101	74	1.68	0.19	1.40	0.03	0.05	0.00
1102	74	QNS	QNS	QNS	QNS	QNS	QNS
1103	74	1.17	0.10	0.99	0.03	0.05	0.00
1104	74	QNS	QNS	QNS	QNS	QNS	QNS
1105	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
1106	74	2.14	0.38	1.64	0.04	0.06	0.01
1107	74	0.82	0.26	0.52	0.02	0.02	0.00
1108	74	3.33	0.19	3.00	0.02	0.10	0.00
1109	74	4.23	0.31	3.67	0.07	0.14	0.01
1110	74	0.87	0.09	0.74	0.01	0.02	0.00

Appendix 11

Individual haematology values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
1101	74	0.00	9.63	138	0.445	46.2	14.3
1102	74	QNS	QNS	QNS	QNS	QNS	QNS
1103	74	0.00	8.56	129	0.418	48.8	15.0
1104	74	QNS	QNS	QNS	QNS	QNS	QNS
1105	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
1106	74	0.01	9.15	139	0.467	51.0	15.2
1107	74	0.00	9.86	147	0.486	49.3	14.9
1108	74	0.02	9.83	142	0.464	47.2	14.4
1109	74	0.04	9.82	142	0.467	47.6	14.5
1110	74	0.00	9.37	133	0.449	48.0	14.2

Appendix 11

Individual haematology values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
1101	74	310	12.8	1213	336.6	3.5	1+
1102	74	QNS	QNS	QNS	QNS	QNS	-
1103	74	308	11.7	743	298.5	3.5	1+
1104	74	QNS	QNS	QNS	QNS	QNS	-
1105	74	CLOT	CLOT	CLOT	CLOT	CLOT	-
1106	74	299	13.4	1252	340.9	3.7	1+
1107	74	302	13.1	976	353.0	3.6	-
1108	74	306	12.2	1245	307.0	3.1	1+
1109	74	305	12.5	1084	290.7	3.0	-
1110	74	297	13.5	1079	327.2	3.5	1+

Appendix 11

Individual haematology values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology		
		ECHINO	PLATELET CLUMPS	WBC MORPH
1101	74	1+	3+	NAF
1102	74	-	-	-
1103	74	4+	3+	NAF
1104	74	-	-	-
1105	74	-	-	-
1106	74	-	2+	NAF
1107	74	-	-	-
1108	74	-	2+	NAF
1109	74	-	-	-
1110	74	2+	2+	NAF

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
2101	74	5.08	1.34	3.37	0.10	0.25	0.01
2102	74	2.47	0.24	2.05	0.06	0.10	0.01
2103	74	2.25	0.32	1.84	0.02	0.05	0.01
2104	74	0.94	0.11	0.80	0.01	0.01	0.00
2105	74	1.46	0.17	1.18	0.03	0.06	0.00
2106	74	QNS	QNS	QNS	QNS	QNS	QNS
2107	74	QNS	QNS	QNS	QNS	QNS	QNS
2108	74	6.73	0.81	5.63	0.13	0.10	0.01
2109	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
2110	74	4.75	1.20	3.01	0.18	0.35	0.01

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
2101	74	0.01	10.11	151	0.493	48.8	15.0
2102	74	0.01	10.15	153	0.494	48.7	15.1
2103	74	0.01	10.67	154	0.519	48.7	14.5
2104	74	0.00	9.37	139	0.469	50.0	14.9
2105	74	0.01	10.54	150	0.484	45.9	14.2
2106	74	QNS	QNS	QNS	QNS	QNS	QNS
2107	74	QNS	QNS	QNS	QNS	QNS	QNS
2108	74	0.05	9.92	147	0.475	47.9	14.8
2109	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
2110	74	0.01	10.13	152	0.478	47.2	15.0

Appendix 11

Individual haematology values: recovery animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
2101	74	307	12.0	1524	344.7	3.4	-
2102	74	310	12.3	880	312.9	3.1	-
2103	74	297	13.6	1115	334.9	3.1	-
2104	74	297	12.5	1212	287.6	3.1	1+
2105	74	310	13.5	1299	332.6	3.2	1+
2106	74	QNS	QNS	QNS	QNS	QNS	-
2107	74	QNS	QNS	QNS	QNS	QNS	-
2108	74	309	13.4	1245	328.9	3.3	-
2109	74	CLOT	CLOT	CLOT	CLOT	CLOT	-
2110	74	317	13.3	1167	285.0	2.8	1+

Appendix 11

Individual haematology values: recovery animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology		
		ECHINO	PLATELET CLUMPS	WBC MORPH
2101	74	-	-	-
2102	74	-	-	-
2103	74	-	-	-
2104	74	2+	1+	NAF
2105	74	-	3+	NAF
2106	74	-	-	-
2107	74	-	-	-
2108	74	-	-	-
2109	74	-	-	-
2110	74	3+	4+	NAF

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
1601	74	5.85	0.52	4.68	0.20	0.40	0.02
1602	74	4.54	0.46	3.89	0.06	0.09	0.01
1603	74	6.56	0.44	5.70	0.05	0.30	0.02
1604	74	3.09	0.52	2.43	0.03	0.08	0.01
1605	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
1606	74	4.40	0.51	3.79	0.02	0.06	0.01
1607	74	3.01	0.41	2.42	0.05	0.11	0.01
1608	74	6.02	0.73	4.64	0.09	0.50	0.01
1609	74	4.79	0.62	3.89	0.06	0.19	0.01
1610	74	7.23	0.76	6.22	0.03	0.17	0.01

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
1601	74	0.03	10.01	149	0.485	48.5	14.9
1602	74	0.03	9.79	155	0.488	49.8	15.8
1603	74	0.04	9.87	156	0.483	49.0	15.8
1604	74	0.01	10.20	155	0.493	48.4	15.2
1605	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
1606	74	0.01	10.55	157	0.502	47.6	14.9
1607	74	0.01	10.39	154	0.495	47.6	14.8
1608	74	0.05	9.31	150	0.472	50.7	16.1
1609	74	0.01	10.51	159	0.489	46.6	15.2
1610	74	0.04	10.03	151	0.483	48.2	15.0

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
1601	74	307	14.2	950	429.6	4.3	1+
1602	74	317	12.9	1231	313.5	3.2	-
1603	74	322	12.4	1178	273.7	2.8	-
1604	74	315	13.2	1248	424.9	4.2	-
1605	74	CLOT	CLOT	CLOT	CLOT	CLOT	-
1606	74	312	12.9	1289	375.6	3.6	-
1607	74	311	14.5	1112	672.0	6.5	-
1608	74	317	12.6	1020	289.8	3.1	1+
1609	74	326	13.1	1130	320.2	3.0	-
1610	74	312	13.9	972	259.4	2.6	-

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Hematology		
		ECHINO	PLATELET CLUMPS	WBC MORPH
1601	74	1+	4+	NAF
1602	74	-	-	-
1603	74	-	-	-
1604	74	-	-	-
1605	74	-	-	-
1606	74	-	-	-
1607	74	-	-	-
1608	74	-	4+	NAF
1609	74	-	-	-
1610	74	-	-	-

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)
2601	74	4.09	0.48	3.37	0.03	0.18	0.01
2602	74	6.01	0.68	5.05	0.06	0.17	0.01
2603	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
2604	74	3.17	0.51	2.46	0.05	0.12	0.01
2605	74	QNS	QNS	QNS	QNS	QNS	QNS
2606	74	5.43	0.71	4.42	0.08	0.15	0.01
2607	74	6.41	0.44	5.75	0.06	0.09	0.02
2608	74	3.97	0.77	3.10	0.02	0.05	0.01
2609	74	QNS	QNS	QNS	QNS	QNS	QNS
2610	74	5.46	0.50	4.57	0.19	0.16	0.01

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology					
		LUC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (L/L)	MCV (fL)	MCH (pg)
2601	74	0.02	8.98	138	0.450	50.2	15.3
2602	74	0.04	9.76	145	0.470	48.2	14.8
2603	74	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
2604	74	0.02	9.87	150	0.482	48.9	15.2
2605	74	QNS	QNS	QNS	QNS	QNS	QNS
2606	74	0.05	9.42	148	0.468	49.7	15.7
2607	74	0.05	10.39	153	0.496	47.8	14.7
2608	74	0.02	10.25	156	0.497	48.5	15.2
2609	74	QNS	QNS	QNS	QNS	QNS	QNS
2610	74	0.03	10.43	162	0.514	49.3	15.5

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology MCHC (g/L)	RDW (%)	PLT (10^9/L)	RETIC (10^9/L)	RETIC (%)	POLY
2601	74	306	14.4	1050	305.5	3.4	1+
2602	74	308	13.3	1012	363.1	3.7	-
2603	74	CLOT	CLOT	CLOT	CLOT	CLOT	-
2604	74	310	14.2	947	329.9	3.3	-
2605	74	QNS	QNS	QNS	QNS	QNS	-
2606	74	316	12.3	1027	302.8	3.2	-
2607	74	308	13.5	809	538.2	5.2	-
2608	74	314	13.2	1179	362.3	3.5	-
2609	74	QNS	QNS	QNS	QNS	QNS	-
2610	74	315	13.1	803	315.1	3.0	-

Appendix 11

Individual haematology values: recovery animals

513351

Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Hematology		
		ECHINO	PLATELET CLUMPS	WBC MORPH
2601	74	2+	4+	NAF
2602	74	-	-	-
2603	74	-	-	-
2604	74	-	-	-
2605	74	-	-	-
2606	74	-	-	-
2607	74	-	-	-
2608	74	-	-	-
2609	74	-	-	-
2610	74	-	-	-

Appendix 12

Individual plasma chemistry values

Explanation pages

Cobas 6000

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
3-Hydroxybutyrate	3-HB	µmol/L	Enzymatic colorimetric
5-Nucleotidase	5-NT	U/L	Enzymatic colorimetric
Alanine Aminotransferase	ALT	U/L	ALT IFCC UV
Albumin	ALB	g/L	Bromcresol green colorimetric
Albumin Rabbit	ALB	g/L	Bromcresol green colorimetric
Alkaline Phosphatase	ALP	U/L	ALP IFCC liquid colorimetric
Amylase	AMYL	U/L	Enzymatic colorimetric
Ammonia	AMM	µg/dL	Enzymatic kinetic
[1]Ammonia	AMMO	µmol/L	Enzymatic kinetic
Aspartate Aminotransferase	AST	U/L	AST IFCC UV
BAL Phospholipids (SI) mmol/L	PLIP	mmol/L	Enzymatic colorimetric
BAL Total Protein (SI) mg/L	TPROT	mg/L	Immunoturbidimetric
Bile Acids Plasma	BILEAC	µmol/L	Enzymatic colorimetric
Bicarbonate	CO2	mmol/L	PEPC enzymatic colorimetric method
Calcium	CA	mmol/L	NM-BAPTA
Chloride	CL	mmol/L	Indirect measurement (Ion selective electrode)
Cholesterol	CHOL	mmol/L	CHOD-PAP enzymatic colorimetric
C3c	C3C	mg/dL	Immunoturbidimetric
C4	C4	mg/dL	Immunoturbidimetric
Creatine Kinase	CK	U/L	CK IFCC UV
CK MB Isoenzyme	CK MB	U/L	Immunological colorimetric.
Creatinine	CREAT	µmol/L	Jaffe kinetic colorimetric. Rate-blanked and compensated
C-Reactive Protein	CRP	mg/dL	Immunoturbidimetric
[1]C-Reactive Protein	CRP	mg/L	Immunoturbidimetric
D-Dimer	DDIM	µg/mL	Immunoturbidimetric
[1]D-Dimer	DDI	mg/L	Immunoturbidimetric
Direct Bilirubin	DBIL	µmol/L	Diazo Method
Gamma-Glutamyl Transferase	GGT	U/L	Nitro-Anilide, Glycylglycine; enzymatic colorimetric
Ferritin	FERR	ng/mL	Immunoturbidimetric
[1]Ferritin	FERR	µg/L	Immunoturbidimetric
Fructosamine	FRUC	µmol/L	Colorimetric
Glucose	GLUC	mmol/L	Hexokinase UV
Glutamate Dehydrogenase	GLDH	U/L	GLDH UV
Glycosylated Haemoglobin Percent	GLY HGB	%	Turbidimetric inhibition immunoassay
Haptoglobin	HAPTO	g/L	Colorimetric
HDL Cholesterol	HDL	mmol/L	Enzymatic colorimetric
Immunoglobulin A	IGA	mg/dL	Immunoturbidimetric
[1]Immunoglobulin A	IgA	g/L	Immunoturbidimetric

Appendix 12

Cobas 6000

Analysed parameter descriptions

Immunoglobulin G	IGG	mg/dL	Immunoturbidimetric
[1]Immunoglobulin G	IgG	g/L	Immunoturbidimetric
Immunoglobulin M	IGM	mg/dL	Immunoturbidimetric
[1]Immunoglobulin M	IgM	g/L	Immunoturbidimetric
Inorganic Phosphate	PHOS	mmol/L	Molybdate -endpoint
Iron	FE	µmol/L	Colorimetric
Lactate	LACT	mmol/L	Enzymatic colorimetric
Lactate Dehydrogenase	LDH	U/L	LDH IFCC UV
LDL Cholesterol	LDL	mmol/L	Enzymatic colorimetric
Lipase	LIPASE	U/L	Enzymatic colorimetric
Magnesium	MG	mmol/L	Colorimetric endpoint method.
Non-Esterified Fatty Acids	NEFA	mmol/L	Enzymatic colorimetric
Potassium	K	mmol/L	Indirect measurement (Ion selective electrode)
Sodium	NA	mmol/L	Indirect measurement (Ion selective electrode)
Sorbitol Dehydrogenase	SDH	U/L	Enzymatic colorimetric
Total Bilirubin	TBIL	µmol/L	DPD colorimetric
Total Ketone Bodies	TOTAL KETONE BODIES	µmol/L	Cyclic enzymatic
Total Protein	TPROT	g/L	Biuret colorimetric
Transferrin	TFERRIN	g/L	Immunoturbidimetric
Triglycerides	TRIG	mmol/L	GPO-PAP enzymatic colorimetric
Unsaturated Iron Binding Capacity	UIBC	µg/dL	Colorimetric
Urea	UREA	mmol/L	Urease kinetic UV
Uric Acid	URIC ACID	µmol/L	Enzymatic colorimetric

[1]Cobas 6000 only

ADVIA Centaur

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Free Triiodothyronine (pg/mL, 1 decimal)	T3FR	pg/mL	Chemiluminescence immunoassay
Free Thyroxine (ng/dL, 2 decimals)	T4FR	ng/dL	Chemiluminescence immunoassay
Triiodothyronine, Total	T3	ng/mL	Chemiluminescence immunoassay
Thyroxine ng/mL	T4	ng/mL	Chemiluminescence immunoassay

Immunoassay

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
50% Complement Haemolytic Activity	CH50	CH50 U Eq/mL	ELISA
Adiponectin (HMW)	ADPNCTN	ng/mL	Mouse specific ELISA
Adiponectin (SI)	ADIP (SI)	mg/L	ELISA
Aldosterone	ALDSTRN	µg/L	ELISA

Appendix 12

Immunoassay

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Bb Fragment of Factor B	BB	mg/L	ELISA
Complement C3a (SI)	C3a	µg/L	ELISA
Complement C3a	C3a	ng/mL	ELISA
Complement Component C4a (SI)	C4a	µg/L	ELISA
Complement Component C4d	C4d	µg/mL	ELISA
Complement Component C4d (SI)	C4d	mg/L	ELISA
Corticosterone	CRTRONE	ng/mL	Mouse/rat specific ELISA
Corticosterone (SI)	CRTRONE	µg/L	ELISA
C-Peptide (ng/mL)	CPEPTIDE	ng/mL	Mouse specific ELISA
C-Reactive Protein	CRP	mg/L	Tridelta canine CRP ELISA
C-Reactive Protein	CRP	mg/L	Life Diagnostic rat CRP ELISA
C-Reactive Protein	CRP	mg/L	Life Diagnostic rabbit CRP
C-Reactive Protein (SI)	CRP	mg/L	ELISA
Glucagon	Glucagon	pmol/L	ELISA
Insulin ug/L	INSULI	µg/L	ELISA
Insulin-like Growth Factor-1	IGF-1	µg/L	R&D Quantakine mouse/rat specific ELISA
Myoglobin	MGB	ng/mL	ELISA
Myoglobin (SI)	MGB	µg/L	ELISA
Osteocalcin ng/mL	OSTEOCALCIN	ng/mL	Rat specific ELISA
Osteocalcin (SI)	OSTEOCALCIN	µg/L	ELISA
Renin (SI)	Ren (SI)	ng/L	ELISA
Serum Amyloid A (SI)	SAA	mg/L	ELISA
Soluble Terminal Component C5 through C9 complex	SC5b-9	ng/mL	ELISA
Complement Complex SC5b-9	SC5b-9	µg/L	ELISA
Somatotrophin;Growth Hormone	GH SOMATRO	µg/L	Demeditec mouse/rat specific ELISA
Testosterone ng/mL	TESTOS	ng/mL	ELISA
Testosterone (SI)	TESTOS	nmol/L	ELISA
Thyroid Stimulating Hormone	TSH	ng/mL	Demeditec rat specific ELISA
Thyroid Stimulating Hormone ng/mL	TSH	ng/mL	ELISA
Urine Cystatin C (SI)	CYSTATC	mg/L	ELISA
Urine Osteopontin (SI)	OPN	mg/L	ELISA

Meso Scale Discovery Sector Imager

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Alpha-2 Macroglobulin	SIA2M	mg/L	Electrochemiluminescent
Alpha-1 Acid Glycoprotein SI	SIAGP	mg/L	Electrochemiluminescent
BAL Alpha-2 Macroglobin	A2M	ug/L	Electrochemiluminescent
BAL Alpha-1 Acid Glycoprotein SI	AGP	ug/L	Electrochemiluminescent

Appendix 12

i-STAT 1

Analysed parameter descriptions

Parameter	Abbreviation	Units	Methodology
Blood pH	pH		i-STAT
Bicarbonate for Blood Gas	HCO3	mmol/L	i-STAT
Partial Pressure Carbon Dioxide	PCO2	mmHg	i-STAT
Carbon Dioxide, Total	TOTAL CO2	mmol/L	i-STAT
Partial Pressure Oxygen	PO2	mmHg	i-STAT
Oxygen Saturation	O2SAT	%	i-STAT
Lactate	LACT	mmol/L	i-STAT
Base Excess	Base Excess	mmol/L	i-STAT
Ionised Calcium	ION CA	mmol/L	i-STAT
Total Hemoglobin g/dL	THGB	g/dL	i-STAT

Calculations

Parameter descriptions

Parameter	Abbreviation	Units	Methodology
Albumin/Globulin ratio	A/G	None	Albumin / Globulin
Globulin	GLOB	g/L	Total Protein – Albumin
Indirect Bilirubin	IBIL	µmol/L	Total Bilirubin – Direct Bilirubin
Total Iron binding Capacity	TIBC	µg/dL	Transferrin*22.75
[2]Total Iron binding Capacity	TIBC	µmol/L	UIBC+Iron
Urea Nitrogen	UREAN	mg/dL	Urea*2.801

[2]Calculations used in Provantis 10 only

Serum and plasma appearance (Reported as SAMQ)

Analysed Parameter Descriptions

Parameter	Abbreviation	Degree is graded as	Methodology
Normal sample	N	Normal	Manual and visual
Haemolysed sample	H	+ = mild ++ = moderate +++ = marked	Manual and visual
Lipaemic sample	L	+ = mild ++ = moderate +++ = marked	Manual and visual
Icterus sample	I	+ = mild ++ = moderate +++ = marked	Manual and visual
Atypical sample	A	Color is identified	Manual and visual

Note: This is a comprehensive list of parameters and abbreviations. All of the parameters and abbreviations listed may not be applicable to this report.

Appendix 12

Clinical pathology data flags

Abbreviation	Description
-	No sample or no result. The exception is Urine Microscopic, Red and White Blood Cell Morphology and Platelet Morphology where it denotes an abnormal finding in one or more parameters
ADQ	Adequate
AVS	Suspected aberrant value
BE0	Volume below 0.1mL
CLOT	Sample clotted
COM	Contaminated with organic material
COME	See comment value excluded
COMI	See comment value included
COMM	Comment added
DEC	Decreased
Exc	Exclude
GFC	Gross fecal contamination present
INC	Increased
INV	Invalid result
IRPS	Presence of abundant plasmodium species
ISH	Result invalid due to severe haemolysis
ISL	Result invalid due to severe lipaemia
L100	Less than 100 cells used to perform differential
LLOQ	Less than lower limit of quantification
MDIFF	Manual differential
NA	Not applicable
NAF	No abnormal findings
NC	Not calculable
NCD	No clot detected
NRBC	WBC corrected for presence of nucleated RBC
NSCH	Not scheduled to be performed
OA	Omitted activity
OOS	Sample analysed outside of established stability, results for information only
NT	Not Taken
QNS	Quantity not sufficient
RSV	Refer to source values
S	Spillage
SAMU	Large number of smudge cells
SNC	Sample not collected
SNR	Sample not received
SVGS	Sample volume greater than specified
SVLS	Sample volume less than specified
TERR	Technical error (explanation required)
TNP	Test not performed
TNR	Test not reported
UNCR	Results are not reproducible
UNEX	Unscheduled data excluded from statistics
UPTD	Unable to perform due to technical difficulty
UTC	Unable to collect

Appendix 12

Clinical pathology data flags

Abbreviation	Description
UTD	Unable to determine
UTDH	Unable to determine due to marked haemolysis
UTDL	Unable to determine due to marked lipaemia
UTDM	Unable to determine results, not confirmed by microscopy
UTDR	Unable to determine results not reproducible
VARR	Assigned value above reportable range
VBRR	Assigned value below reportable range
VNC	Value not calculable
X	Excluded from mean

Note: This is a comprehensive list of clinical pathology data flags. All of the data flags listed may not be applicable to this report.

Assigned values denoted with the data flags VARR or VBRR have been used for statistical/group mean analysis where appropriate.

Additional abbreviations

Abbreviation	Description
RC	Result comment

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
1011	45	127	76	73	77.6	1.3 [a]	3.7
1012	45	65	52	71	12.3	1.3 [a]	3.2
1013	45	55	46	49	14.2	1.3 [a]	2.8
1014	45	67	70	71	23.4	1.3 [a]	4.3
1015	45	81	70	80	20.6	1.3 [a]	2.6
1016	45	46	46	59	12.2	1.3 [a]	1.5
1017	45	52	47	54	32.5	1.3 [a]	1.3
1018	45	74	72	64	58.5	3.1	1.8
1019	45	60	72	58	9.5	1.3 [a]	4.8
1020	45	95	91	62	30.0	1.3 [a]	3.0

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
1011	45	7.8	8 [a]	13.12	3.14	1.03	52.5
1012	45	7.5	8 [a]	10.83	3.35	1.84	49.1
1013	45	5.4	8 [a]	10.04	3.82	1.31	49.9
1014	45	8.2	8 [a]	8.70	3.55	2.70	50.6
1015	45	7.7	8 [a]	11.45	3.54	1.59	49.2
1016	45	6.2	8 [a]	11.02	4.13	1.33	49.1
1017	45	6.4	8 [a]	11.00	3.63	0.95	48.9
1018	45	5.3	8 [a]	9.15	2.46	1.22	45.2
1019	45	7.5	8 [a]	9.49	2.81	1.21	47.8
1020	45	7.6	8 [a]	8.32	2.85	0.75	49.6

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
1011	45	34.1	18.4	1.9	2.35	150	4.2
1012	45	30.6	18.5	1.7	2.28	151	4.3
1013	45	30.6	19.3	1.6	2.35	150	5.0
1014	45	33.2	17.4	1.9	2.52	150	4.5
1015	45	30.0	19.2	1.6	2.26	151	4.3
1016	45	31.2	17.9	1.7	2.43	149	5.8
1017	45	32.5	16.4	2.0	2.64	154	5.1
1018	45	28.6	16.6	1.7	2.31	151	5.4
1019	45	30.5	17.3	1.8	2.40	151	4.7
1020	45	31.6	18.0	1.8	2.51	152	4.6

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
1011	45	109	2.05	N
1012	45	108	2.04	N
1013	45	109	2.10	N
1014	45	108	1.66	N
1015	45	111	1.83	N
1016	45	104	1.75	N
1017	45	111	1.75	N
1018	45	106	1.99	N
1019	45	107	2.40	N
1020	45	108	2.33	N

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
2011	45	83	64	57	36.9	1.3 [a]	1.4
2012	45	50	35	54	8.2	1.3 [a]	1.7
2013	45	107	69	43	41.2	1.3 [a]	1.1
2014	45	53	37	71	20.0	1.3 [a]	1.8
2015	45	124	90	87	98.5	1.3 [a]	4.1
2016	45	83	75	58	15.8	1.3 [a]	1.5
2017	45	102	58	73	29.5	1.3 [a]	1.9
2018	45	77	83	47	143.6	1.3 [a]	2.2
2019	45	47	49	45	4.6	1.3 [a]	1.7
2020	45	82	51	51	20.8	1.3 [a]	1.7

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
2011	45	9.9	8 [a]	10.82	3.84	1.36	52.4
2012	45	7.7	8 [a]	9.95	3.95	3.01	52.6
2013	45	7.0	8 [a]	7.46	3.50	2.46	49.0
2014	45	8.3	8 [a]	10.04	3.83	2.00	49.6
2015	45	5.8	8 [a]	11.42	3.71	0.81	54.0
2016	45	7.2	8 [a]	11.16	3.16	2.11	52.1
2017	45	7.4	8 [a]	9.14	3.38	1.71	48.1
2018	45	7.9	8 [a]	9.44	3.27	2.33	51.3
2019	45	6.0	8 [a]	9.78	3.01	1.07	47.9
2020	45	6.6	8 [a]	10.55	3.61	1.42	50.4

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
2011	45	29.9	22.5	1.3	2.31	150	4.1
2012	45	29.7	22.9	1.3	2.48	150	4.8
2013	45	26.4	22.6	1.2	2.43	151	5.0
2014	45	29.6	20.0	1.5	2.46	151	4.3
2015	45	34.6	19.4	1.8	2.38	150	4.3
2016	45	28.9	23.2	1.2	2.49	154	4.7
2017	45	27.2	20.9	1.3	2.56	156	4.7
2018	45	30.4	20.9	1.5	2.52	153	4.4
2019	45	27.7	20.2	1.4	2.35	147	5.2
2020	45	29.2	21.2	1.4	2.47	151	4.6

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
2011	45	111	1.73	N
2012	45	107	1.30	N
2013	45	110	1.59	N
2014	45	109	1.52	N
2015	45	108	2.00	N
2016	45	111	1.78	N
2017	45	110	2.13	N
2018	45	108	2.20	N
2019	45	104	2.16	N
2020	45	106	2.35	N

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
1511	45	116	61	91	27.9	1.3 [a]	5.3
1512	45	96	39	70	11.0	1.3 [a]	2.6
1513	45	86	30	125	9.4	1.3 [a]	2.9
1514	45	77	27	101	10.0	1.3 [a]	3.8
1515	45	351	72	84	17.1	1.3 [a]	3.3
1516	45	105	47	135	13.8	1.3 [a]	2.8
1517	45	140	76	105	16.7	1.3 [a]	4.1
1518	45	155	78	88	57.5	1.3 [a]	10.4
1519	45	69	34	108	8.9	1.3 [a]	6.9
1520	45	67	31	86	9.4	1.3 [a]	3.5

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
1511	45	7.2	8 [a]	8.75	1.75	2.56	51.3
1512	45	6.7	8 [a]	9.11	2.16	2.47	46.9
1513	45	5.0	8 [a]	10.69	2.62	4.91	50.1
1514	45	5.4	8 [a]	12.28	2.98	1.82	52.8
1515	45	4.9	8 [a]	12.11	3.61	2.42	51.0
1516	45	8.4	8 [a]	10.10	1.67	2.31	47.5
1517	45	6.2	8 [a]	11.02	2.45	3.22	51.7
1518	45	9.3	8 [a]	11.53	2.13	1.49	51.0
1519	45	7.0	8 [a]	10.74	2.63	2.77	52.1
1520	45	5.1	8 [a]	13.06	2.05	0.72	46.7

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
1511	45	32.6	18.7	1.7	2.35	147	5.0
1512	45	34.2	12.7	2.7	2.39	153	4.7
1513	45	33.5	16.6	2.0	2.56	151	4.6
1514	45	36.3	16.5	2.2	2.46	149	5.1
1515	45	34.8	16.2	2.1	2.51	149	4.0
1516	45	35.2	12.3	2.9	2.53	150	4.3
1517	45	35.8	15.9	2.3	2.56	151	4.5
1518	45	36.9	14.1	2.6	2.46	153	4.0
1519	45	36.4	15.7	2.3	2.47	153	5.1
1520	45	32.8	13.9	2.4	2.34	152	4.5

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
1511	45	110	1.33	N
1512	45	112	1.24	N
1513	45	107	2.26	N
1514	45	106	2.85	N
1515	45	107	2.10	N
1516	45	110	1.52	N
1517	45	109	1.86	N
1518	45	109	2.45	N
1519	45	108	2.48	N
1520	45	113	2.18	N

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
2511	45	67	33	81	6.4	1.3 [a]	5.5
2512	45	60	28	92	5.7	1.3 [a]	2.0
2513	45	62	35	60	9.8	1.3 [a]	2.3
2514	45	75	32	69	8.6	1.3 [a]	5.5
2515	45	89	32	55	8.3	1.3 [a]	1.7
2516	45	64	28	68	6.5	1.3 [a]	2.1
2517	45	66	26	64	7.2	1.3 [a]	3.2
2518	45	59	24	76	4.7	1.3 [a]	7.4
2519	45	60	35	79	11.9	1.3 [a]	1.5
2520	45	85	38	73	19.9	1.3 [a]	2.1

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
2511	45	5.8	8 [a]	9.65	2.36	1.67	46.7
2512	45	5.4	17	11.69	2.09	0.98	53.1
2513	45	5.1	16	10.26	1.73	1.85	51.3
2514	45	7.9	8 [a]	13.37	1.83	1.52	49.9
2515	45	5.5	8 [a]	11.00	2.21	1.39	49.8
2516	45	6.8	8 [a]	10.32	2.78	2.30	52.6
2517	45	5.9	8 [a]	11.06	1.97	1.07	47.6
2518	45	5.4	15	11.69	1.96	1.31	45.3
2519	45	6.5	8 [a]	14.64	1.83	0.48	53.2
2520	45	6.2	8 [a]	13.15	2.34	0.37	50.2

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
2511	45	27.4	19.3	1.4	2.49	147	4.5
2512	45	33.0	20.1	1.6	2.44	147	4.5
2513	45	34.3	17.0	2.0	2.52	148	4.4
2514	45	32.5	17.4	1.9	2.49	149	3.6
2515	45	31.6	18.2	1.7	2.57	150	3.5
2516	45	33.4	19.2	1.7	2.45	148	4.9
2517	45	31.4	16.2	1.9	2.40	146	4.7
2518	45	28.5	16.8	1.7	2.45	148	4.1
2519	45	32.2	21.0	1.5	2.40	149	4.7
2520	45	29.5	20.7	1.4	2.50	147	4.4

Appendix 12

Individual plasma chemistry values: main study animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
2511	45	105	1.75	N
2512	45	106	1.91	N
2513	45	105	1.79	N
2514	45	107	1.60	N
2515	45	107	2.02	N
2516	45	106	1.16	N
2517	45	107	1.55	N
2518	45	108	1.88	N
2519	45	111	2.52	N
2520	45	109	2.34	N

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
1111	74	57	70	54	9.5	2.5	2.7
1112	74	60	57	133	17.3	1.3 [a]	3.8
1113	74	51	53	67	11.9	1.3 [a]	3.3
1114	74	46	68	54	14.2	3.4	1.7
1115	74	47	35	48	9.6	1.3 [a]	1.1
1116	74	67	88	51	46.7	1.3 [a]	2.1
1117	74	38	32	48	24.2	2.8	1.4
1118	74	45	42	61	11.1	1.3 [a]	1.3
1119	74	61	78	56	23.2	2.7	2.5
1120	74	73	51	64	19.2	3.0	QNS

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
1111	74	7.3	8 [a]	9.27	3.50	3.11	51.2
1112	74	10.7	8 [a]	11.90	3.31	3.97	48.7
1113	74	7.0	8 [a]	10.89	2.46	1.74	48.3
1114	74	8.4	8 [a]	10.31	4.69	2.83	50.5
1115	74	9.0	8 [a]	11.00	4.55	2.58	51.4
1116	74	8.5	8 [a]	9.95	4.10	3.30	46.1
1117	74	6.0	8 [a]	12.22	3.27	1.34	47.0
1118	74	7.2	8 [a]	9.28	2.76	1.67	44.7
1119	74	5.5	8 [a]	11.14	3.25	2.56	49.0
1120	74	5.4	8 [a]	10.93	2.84	1.74	49.3

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
1111	74	32.0	19.2	1.7	2.49	147	4.6
1112	74	30.7	18.0	1.7	2.45	150	3.9
1113	74	31.7	16.6	1.9	2.35	148	4.4
1114	74	33.8	16.7	2.0	2.37	150	4.8
1115	74	33.8	17.6	1.9	2.39	152	4.5
1116	74	29.3	16.8	1.7	2.47	150	4.5
1117	74	29.4	17.6	1.7	2.47	147	4.8
1118	74	28.1	16.6	1.7	2.30	150	4.6
1119	74	30.6	18.4	1.7	2.34	148	4.8
1120	74	32.2	17.1	1.9	2.46	149	4.7

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
1111	74	107	1.81	N
1112	74	109	1.99	N
1113	74	109	1.86	N
1114	74	108	1.75	N
1115	74	110	1.73	N
1116	74	110	1.69	N
1117	74	108	1.53	N
1118	74	107	1.54	N
1119	74	106	1.75	N
1120	74	106	1.67	N

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
2111	74	89	86	54	26.0	2.5	5.0
2112	74	48	57	41	10.3	1.3 [a]	3.1
2113	74	44	29	36	8.4	2.9	4.2
2114	74	79	58	53	28.8	1.3 [a]	1.4
2115	74	38	40	57	15.1	1.3 [a]	1.3
2116	74	53	48	66	9.6	2.6	6.0
2117	74	46	47	49	15.2	1.3 [a]	2.3
2118	74	64	132	54	16.2	3.6	2.3
2119	74	55	47	70	33.2	3.4	4.8
2120	74	62	46	79	21.6	1.3 [a]	1.6

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
2111	74	5.5	8 [a]	10.41	3.23	1.95	50.8
2112	74	7.8	8 [a]	10.67	3.37	2.53	49.9
2113	74	6.0	8 [a]	13.07	4.09	1.22	52.5
2114	74	6.9	8 [a]	8.78	2.24	1.10	47.8
2115	74	6.9	8 [a]	13.39	3.13	1.71	50.9
2116	74	5.7	8 [a]	12.33	2.61	1.26	49.1
2117	74	5.7	8 [a]	10.29	2.81	0.70	45.5
2118	74	6.0	8 [a]	12.46	3.34	1.77	52.4
2119	74	6.0	8 [a]	9.96	3.44	0.98	45.9
2120	74	9.2	8 [a]	6.88	3.57	0.68	51.8

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
2111	74	30.6	20.2	1.5	2.45	149	4.3
2112	74	31.4	18.5	1.7	2.45	150	4.3
2113	74	32.8	19.7	1.7	2.61	148	4.5
2114	74	30.9	16.9	1.8	2.60	153	4.2
2115	74	31.8	19.1	1.7	2.43	148	4.2
2116	74	31.3	17.8	1.8	2.38	149	4.3
2117	74	29.4	16.1	1.8	2.37	152	4.3
2118	74	34.9	17.5	2.0	2.44	148	5.1
2119	74	28.9	17.0	1.7	2.29	148	5.1
2120	74	34.8	17.0	2.0	2.43	152	3.6

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Male

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
2111	74	106	1.52	N
2112	74	107	2.54	N
2113	74	106	2.12	N
2114	74	110	2.84	N
2115	74	108	1.76	N
2116	74	108	2.64	N
2117	74	110	3.11	N
2118	74	107	1.91	N
2119	74	108	2.21	N
2120	74	111	2.27	N

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
1611	74	68	32	85	14.1	1.3 [a]	6.7
1612	74	58	41	70	19.2	1.3 [a]	5.9
1613	74	54	24	71	10.4	1.3 [a]	12.9
1614	74	58	25	55	12.5	1.3 [a]	1.5
1615	74	80	58	87	52.5	1.3 [a]	3.5
1616	74	75	51	99	14.1	1.3 [a]	2.5
1617	74	51	30	84	6.3	2.5	QNS
1619	74	92	67	77	12.9	1.3 [a]	2.9
1620	74	43	26	72	6.8	1.3 [a]	2.7

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
1611	74	7.5	8 [a]	11.33	2.51	3.79	47.3
1612	74	5.3	8 [a]	14.00	2.91	0.70	48.2
1613	74	6.8	8 [a]	12.88	1.43	0.76	46.5
1614	74	6.2	8 [a]	12.86	2.61	1.82	49.9
1615	74	7.2	8 [a]	12.36	2.35	1.85	45.9
1616	74	4.3	8 [a]	9.80	2.68	0.58	48.3
1617	74	5.1	QNS	QNS	3.18	QNS	QNS
1619	74	5.8	8 [a]	10.79	2.73	0.45	48.4
1620	74	5.2	8 [a]	13.40	2.54	0.97	50.6

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
1611	74	35.5	11.8	3.0	2.52	151	3.8
1612	74	35.6	12.6	2.8	2.47	149	3.8
1613	74	34.2	12.3	2.8	2.39	146	4.0
1614	74	34.7	15.2	2.3	2.37	143	3.7
1615	74	32.4	13.5	2.4	2.44	146	4.3
1616	74	36.2	12.1	3.0	2.42	147	4.6
1617	74	38.7	QNS	QNS	2.34	145	4.5
1619	74	36.5	11.9	3.1	2.46	148	4.6
1620	74	36.4	14.2	2.6	2.41	146	4.1

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 1	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
1611	74	110	2.40	N
1612	74	108	2.98	N
1613	74	110	2.57	N
1614	74	103	2.06	N
1615	74	110	1.66	N
1616	74	107	2.65	N
1617	74	107	QNS	N
1619	74	108	2.39	N
1620	74	106	2.32	N

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry AST (U/L)	ALT (U/L)	ALP (U/L)	GLDH (U/L)	TBIL (umol/L)	BILEAC (umol/L)
2611	74	51	28	61	17.4	1.3 [a]	2.1
2612	74	55	24	91	9.7	1.3 [a]	3.3
2613	74	71	42	90	11.6	1.3 [a]	14.3
2614	74	58	33	96	15.2	1.3 [a]	5.2
2615	74	69	21	63	10.7	1.3 [a]	1.7
2616	74	57	25	89	13.8	1.3 [a]	1.9
2617	74	75	51	57	QNS	QNS	QNS
2618	74	92	91	83	60.8	2.6	2.8
2619	74	55	34	104	15.5	1.3 [a]	2.0
2620	74	40	27	52	8.7	1.3 [a]	4.0

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		UREA (mmol/L)	CREAT (umol/L)	GLUC (mmol/L)	CHOL (mmol/L)	TRIG (mmol/L)	TPROT (g/L)
2611	74	4.8	8 [a]	12.25	2.55	0.66	51.7
2612	74	5.7	8 [a]	13.46	1.47	1.36	49.0
2613	74	7.3	8 [a]	10.74	1.91	2.48	48.0
2614	74	6.4	8 [a]	14.03	2.81	3.09	48.8
2615	74	4.4	8 [a]	13.08	3.36	0.91	49.8
2616	74	5.4	8 [a]	10.74	2.94	1.85	52.9
2617	74	QNS	QNS	QNS	QNS	QNS	QNS
2618	74	6.9	8 [a]	12.28	1.17	1.05	44.9
2619	74	5.9	8 [a]	10.33	2.08	0.89	50.5
2620	74	4.9	8 [a]	13.04	3.13	1.01	51.8

[a] [RC:Assigned value below the reportable range]

Appendix 12

Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry					
		ALB (g/L)	GLOB (g/L)	A/G (ratio)	CA (mmol/L)	NA (mmol/L)	K (mmol/L)
2611	74	35.7	16.0	2.2	2.44	148	4.3
2612	74	34.6	14.4	2.4	2.44	148	3.9
2613	74	35.0	13.0	2.7	2.41	150	3.5
2614	74	32.6	16.2	2.0	2.49	145	3.4
2615	74	33.3	16.5	2.0	2.31	143	4.4
2616	74	36.4	16.5	2.2	2.49	147	4.6
2617	74	36.9	QNS	QNS	QNS	145	4.2
2618	74	34.1	10.8	3.2	2.20	145	4.5
2619	74	33.8	16.7	2.0	2.31	146	5.0
2620	74	33.1	18.7	1.8	2.32	141	4.8

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Individual plasma chemistry values: recovery animals

513351
Sex: Female

70 ul Group 2	Day(s) Relative to Start Date	Reporting Biochemistry		
		CL (mmol/L)	PHOS (mmol/L)	SAMQ
2611	74	109	2.79	N
2612	74	109	2.37	N
2613	74	112	1.87	N
2614	74	106	2.19	N
2615	74	105	1.86	N
2616	74	107	2.47	N
2617	74	106	QNS	N
2618	74	112	1.84	N
2619	74	109	2.32	N
2620	74	103	2.26	N

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Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

FINAL PHASE REPORT

AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

Immunogenicity Bioanalysis

Study Number: 513351

AstraZeneca Phase Number:

2020-AZD1222-0217

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Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

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1 PERSONNEL, KEY DATES AND DATA LOCATION

Study Director:	
Study Director and Test Facility Address:	
Telephone No.	
Email Address:	
Sponsor:	AstraZeneca R&D Cambridge
Sponsor Address:	da Vinci Building Melbourn Science Park Cambridge Road Melbourn Hertfordshire SG8 6HB UK
Principal Investigator:	
Test Site Address:	
Telephone Number:	
Email Address:	
Key Personnel:	
Dates of Phase:	
Date of first data collation against phase:	01-Oct-2020 (first sample receipt)
Bioanalytical Experimental Start Date:	24-Nov-2020
Bioanalytical Experimental Completion Date:	26-Nov-2020

Location of Raw Data, Phase Related Documentation, Phase Report and Samples

This final phase report has been compiled from original raw data generated at AstraZeneca, Cambridge, UK between the experimental dates stated in Section 1. On completion of the Phase all raw data and study related documents generated during the Phase of this study, including a copy of the Phase Plan (and all associated amendments), and Final Phase Report, will be stored initially in the archives at AstraZeneca, Cambridge, UK. Periodically records

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will be transferred to an off-site contract archive facility, Qualogy (UK) as per the Global Retention and Destruction (GRAD) schedule.

Study samples are stored initially in Integrated Bioanalysis laboratory at AstraZeneca, Cambridge, UK. Periodically material may be transferred to an off-site contract archive facility, Cryostore, UK for a period of at least 2 years or as stated in the Study Protocol.

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2 COMPLIANCE STATEMENT

The work described in this Bioanalytical Phase of the study was conducted in compliance with the OECD Principles of GLP (ENV/MC/CHEM) (98)17 (1997), as implemented at the national level in the UK GLP Regulations, Statutory Instrument 3106 (1999), as amended by Statutory Instrument 994 (Codification Amendments Etc.) (2004).

This Bioanalytical Phase of the study was performed according to Standard Operating Procedures (SOPs) and following an approved Phase Plan.

I accept responsibility for the validity of the data generated.

I declare that the work described was performed under my supervision and that the Phase Report provides a true and accurate record of the methods used and the results obtained.

08Dec2020

Date

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3 QUALITY ASSURANCE STATEMENT

Study Number: 513351

Study Title: AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

Study Phase: Immunogenicity Bioanalysis

QA has monitored this study phase and reviewed this phase report.

The phase report is considered to accurately describe the methods and procedures used in this study phase and the reported results accurately and completely reflect the raw data of the study phase.

Audits of this study phase were carried out on the following dates. Findings were reported to the Study Director, Principal Investigator and to Management.

Audit	Audit Dates	Findings reported to SD, PI and Management
Protocol Review and Amendments 1 to 8	18 Nov 2020	18 Nov 2020
Phase Plan Review	18 Nov 2020	19 Nov 2020
Protocol Review Amendments 9 and 10	25 – 26 Nov 2020	02 Dec 2020
Sample Analysis	26 Nov 2020	02 Dec 2020
Phase Report Review	01 – 02 Dec 2020	02 Dec 2020

Facilities relevant to this type of study phase are audited annually. Findings are reported to Test Site Management.

Signature: s 22

Date: 08 December 2020

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4 SUMMARY

AZD1222 is a vaccine against COVID-19 and encodes the spike protein of the SARS-CoV-2 coronavirus. The bioanalysis for the relative quantitative detection of IgG antibodies against SARS-CoV-2 spike protein in murine serum was evaluated in samples originating from Study 513351.

The inter-assay accuracy for calibration standards within limits of quantification ranged from -6.8 to 3.6% RE with precision ≤ 5.8% CV. The inter-assay accuracy for batch acceptance QC samples ranged from -19.3 to 0.3% RE with precision ≤ 15.6% CV indicating acceptable performance during the study.

Data for pre-treatment samples from all animals were negative for IgG against the SARS-CoV-2 spike protein. Following administration of AZD1222 all animals demonstrated ser-conversion with measurable levels of IgG at Day 22 sustained through Day 43 and Day 74.

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5 ABBREVIATIONS

AAPS	American Association of Pharmaceutical Scientists
AU	Arbitrary Units
CDER	Centre for Drug Evaluation and Research
CV (%)	Co-efficient of Variation (Precision)
DPBS	Dulbecco's Phosphate Buffered Saline
ECL	Electrochemiluminescence
EMA	European Medicines Agency
GLP	Good Laboratory Practice
GRAD	Global Retention and Destruction
HQC	High Quality Control
ID	Identification
IgG	Immunoglobulin G
LQC	Low Quality Control
Ltd	Limited
MQC	Mid Quality Control
N/A	Not Applicable
MRD	Minimum Required Dilution
MSD	Meso Scale Discovery
OECD	Organisation for Economic Co-operation and Development
PBS	Phosphate Buffered Saline
QC	Quality Control
% RE	Relative Error
SOP	Standard Operating Procedure

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Std	Calibration Standard
Std Dev	Standard Deviation
UK	United Kingdom
US	United States
Vol.	Volume

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6 INTRODUCTION

6.1 Bioanalytical Phase Objectives

The purpose of this bioanalytical phase was the detection of IgG antibodies against SARS-CoV-2 spike protein in murine serum samples, following administration of AZD1222 (ChAdOx1-nCovd-19) within study 513351; a 6 week intermittent dosing intramuscular vaccine toxicity study in the mouse with a 4 week recovery. The Test Facility for Study 513351 was Charles River Laboratories Edinburgh Ltd, UK. AZD1222 is under development by AstraZeneca as a potential COVID-19 vaccine.

The relative-quantitative method used in this bioanalytical phase was validated under AstraZeneca study number 2020-AZD1222-0213 with partial validation conducted under study 2020-AZD1222-0227.

This bioanalytical phase report details the relative serum concentrations of IgG against SARS-CoV-2 spike protein at predetermined timepoints during study 513351.

7 REFERENCES

Report 2020-AZD1222-0213: Validation of an Electrochemiluminescence (ECL) Immunoassay for the Detection of IgG Antibodies against SARS-CoV-2 Spike Protein in Mouse Serum.

Report 2020-AZD1222-0227: Partial Validation of an Electrochemiluminescence (ECL) Immunoassay for the Detection of IgG Antibodies against SARS-CoV-2 Spike Protein in Mouse Serum.

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8 MATERIALS AND EQUIPMENT

8.1 Critical Reagents

8.1.1 Anti-SARS-CoV-2 Antibody - Calibrator

Company Code/Name:	CV191074 Murine IgG2a
Concentration:	1.17 mg/mL
Lot Number:	CV191074-003 (BET280820)
Re-test Date:	Assigned 27-Oct-2022
Storage Conditions:	Nominally -80°C
Source:	AstraZeneca Biologics Expression Team Cambridge, UK

8.1.2 SARS-CoV-2 Trimeric Spike Protein

SARS-CoV-2 Trimeric spike protein was supplied by Biopharmaceutical Development, AstraZeneca and stored in single-use aliquots in a freezer set to -80ºC.

- Batch number SP20-040, re-test date 21-May-2022

8.1.3 Detection Antibody

SULFO-TAG labelled goat anti-mouse antibody (product number: R32AC-1) was supplied by MSD (US) and stored at 2 to 8ºC. The following batch was employed in this phase:

- Batch number W0019841S, expiry date 30-Sep-2023

8.1.4 Control Biological Matrix

Pooled mouse serum was supplied by BioIVT (UK) with appropriate safety information and stored at nominally -80°C. The following batch was employed in this phase:

- Batch number MSE303394, re-test date 29-Oct-2023

8.2 Other Reagents

8.2.1 MSD 96 Well High Bind Plates

MSD 96 well high bind plates (product number: L15XB) were obtained from MSD and stored as per manufacturer's instructions at room temperature. The following batch was employed in this phase:

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- Batch number 22JOEA, expiry date 30-Jun-2021

8.2.2 Blocker Casein in PBS (Assay Diluent)

Blocker Casein in PBS (Assay Diluent) (product number: 37528) was obtained from Thermo Fisher Scientific and stored as per manufacturer's instructions at 2 to 8ºC. The following batch was employed in this phase:

- Batch number VE301373, expiry date 09-Feb-2021

8.2.3 MSD® Gold Read Buffer B

Read Buffer B (product number: R60AM) was supplied by MSD® and stored as per manufacturer's instructions at room temperature. The following batch was employed in this phase:

- Batch number YO800010, expiry date 31-Dec-2022

8.3 Critical Analytical Equipment and Validated Software

Equipment	Description
MSD SECTOR S 600	MSD, asset number: 200034966, serial number: 1201150625310
MSD Analysis Software	Discovery Workbench 4.0.12

Table 8.3-1 Key Equipment List

Equipment	Description	Asset ID
MSD SECTOR S 600	MSD plate reader	Asset number: 200034966, Serial number: 1201150625310
MSD Analysis Software	Discovery Workbench 4.0.12	N/A
+2°C to +8°C Refrigerator	BioCompact II RR210	200030594 200027873
-80°C Freezer	Sanyo MDF-U7386S -80°C Freezer	200032567 200032568
-80°C Freezer	New Brunswick U725-G	200042115
Plate Washer	BioTek ELx405	DS1436

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9 IMMUNOGENICITY METHOD

The analytical method was validated in study 2020-AZD1222-0213 with partial validation in study 2020-AZD1222-0227.

Validation procedures followed were based upon:

- Guidance for Industry, Bioanalytical Method Validation, (CDER) May 2018
- Bioanalytical Methods Validation for Macromolecules: Summary Report reported by Krys J. Miller *et al.* (2001), *Pharm. Res*., Vol. 18, No.9, 1373-1383
- Recommendations for the Bioanalytical Method Validation of Ligand-Binding Assay to Support Pharmacokinetic Assessments of Macromolecules by DeSilva *et al.* (2003), *Pharm. Res.,* Vol. 20, No.11
- Bioanalytical Method Validation for Macromolecules Workshop/Conference Report, AAPS, 05/2006
- Guideline on Bioanalytical Method Validation (EMA), effective Feb 2012
- Fit-for-Purpose Method Development and Validation for Successful Biomarker Measurement by Lee *et al.* (2006), *Pharm. Res.*, Vol. 23, No.2

9.1 Context of Use

The purpose of the assay was to demonstrate seroconversion of animals against the SARS-CoV-2 spike protein following immunisation with AZD1222. The assay was a relative-quantitative immunoassay in murine serum performed on the MSD platform, using a monoclonal antibody against the SARS-CoV-2 spike protein as calibrator. Data from the assay were required to demonstrate exposure in the animals to the vaccine, seroconversion against the spike protein and an increase in antibody level following a boost immunisation.

9.2 Immunogenicity Analytical Procedure

For the method a sequential direct format ECL immunoassay is used. MSD high bind microtitre plates were coated with recombinant spike protein trimer from SARS-CoV-2 which captured any anti-SARS-CoV-2 immunoglobulins present in the calibrators, QC, and test samples. IgG was then detected using a SULFO-TAG-labelled goat anti-mouse antibody to form an immune complex. The complex was then detected by the addition of MSD Read Buffer to the plate and subsequent excitation of the SULFO-TAG label. The quantity of light detected correlated to the level of anti-SARS-CoV-2 IgG present in the sample.

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A full description of the assay procedure is presented in Appendix 1.

9.3 Preparation of Reagents

The preparation of reagents necessary for the assay are included in the assay procedure in Appendix 1. Exact preparation details were recorded in the raw data.

9.4 Preparation of Calibration Standards

Anti-SARS-CoV-2 calibration standard curve was prepared in mouse serum as detailed in Table 9.4-1.

Table 9.4-1 Preparation of Calibration Standards

Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	ID	Concentration (ng/mL)**
CV191074 (1.17 mg/mL)	10	81.4	Std1	128000*
Std1	30	30	Std2	64000*
Std2	30	30	Std3	32000
Std3	30	30	Std4	16000
Std4	30	30	Std5	8000
Std5	30	30	Std6	4000
Std6	30	30	Std7	2000
Std7	30	30	Std8	1000
Std8	30	30	Std9	500
Std9	30	30	Std10	250
Std10	30	30	Std11	125*
N/A	N/A	30	Blank	0.00

*Anchor points **Calculation rounded to 3 significant figures

9.5 Preparation of Quality Control (QC) Samples

Validation Control samples from study 2020-AZD1222-0227 were reassigned as Quality Control samples for use in this bioanalytical phase. QC samples were assigned batch number 8223-18-070 and re-test date 08-Nov-2022. Anti-SARS-CoV-2 quality control (QC) samples were prepared by spiking the CV191074 calibrator antibody (Section 8.1.1) into mouse serum as detailed in Table 9.5-1. QC samples were aliquoted and stored in a freezer set at -80ºC.

Table 9.5-1 Preparation of Quality Controls

Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	Concentration (ng/mL)	ID
CV191074	36	1720	24000	HQC

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Table 9.5-1 Preparation of Quality Controls

Spiking Solution	Volume Spike (µL)	Vol. Mouse Serum (µL)	Concentration (ng/mL)	ID
(1.17 mg/mL)				
HQC	200	1400	3000	MQC
HQC	40	1495	625	LQC

9.6 Final Preparation of Standards, Controls and Samples

All standards, QC, and study samples were subject to a 100-fold minimum required dilution (MRD) in assay diluent (Blocker Casein in PBS) prior to analysis. Exact preparation details were documented in the raw data.

9.7 Study Sample Preparation

All study samples underwent the 100-fold MRD. Where required, samples were diluted up to a further 400-fold in 1% murine serum. Samples first underwent the 100-fold MRD with subsequent dilutions post-MRD prepared by diluting in 1% murine serum. All samples were tested in duplicate (n=2 replicates).

For all time points except Pretreatment, samples were analysed at both 50- and 400-fold dilutions as a mechanism to ensure a valid result was generated given low volume of available sample. Where both the 50-fold and 400-fold dilutions produced acceptable data the reported result was taken from the 50-fold dilution (as the lowest diluted sample).

9.8 Acceptance Criteria for Calibration Standards

For each assay a standard curve was analysed in duplicate (n=2 replicates). Standard curve precision and accuracy fulfilled the following criteria; a minimum of 75% calibration standards (minimum of 6 non-zero standards within the working range) had ≤30% CV and ≤± 30% RE. Anchor points (Standards 1 and 2 (128000 and 64000 ng/mL respectively) and Standard 11 (125 ng/mL) were not subject to these criteria.

9.9 Acceptance Criteria for Analytical Assay Runs

Acceptability criteria for all QC samples were set where frozen QC samples demonstrated a precision of ≤ 30% CV between duplicate replicates (n=2) and a measured concentration with accuracy of ±≤ 35% RE from the nominal concentration.

Accuracy (% RE) was assessed using the following equation:

% RE = [(Observed value – Nominal Concentration)/Nominal Concentration)] x 100

Precision (% CV) was determined using the equation:

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% CV = (Std Dev of Mean Calculated Concentration/Mean Calculated Concentration) x100

Two sets of QCs were included in each analytical run. A minimum of four out of the six QC samples were required to fulfil accuracy and precision acceptance criteria as above for the run to be deemed acceptable. However, if the two failed QC samples were of the same concentration the run was classed as a failed run.

9.10 Acceptance Criteria for Immunogenicity Samples

Acceptance criteria for measurement of IgG against SARS-CoV-2 spike protein in study samples was a precision of ≤ 30% CV between duplicate replicates (n=2). Only sample data from accepted analytical assay runs were reported.

9.11 Data Processing

All data collection, processing (statistics and quantification) and storage was performed using the data reduction software package Discovery Workbench 4.0.12 or Microsoft® Excel (Office 2016). The data regression used a four parameter curve fit with $1/y^2$ weighting. All test sample concentration data were reported to 3 decimal places in AU/mL following a conversion factor of 0.001 (where AU = arbitrary units). All calibration standard and QC data were reported in ng/mL to the nearest whole number. All precision (% CV) and accuracy (% RE) data were reported to one decimal place. Minor discrepancies between the raw data and reported data are accounted for by data rounding between the Discovery Workbench Software and Microsoft® Excel.

10 STUDY SAMPLES

10.1 Sample Receipt

The following shipments were received for study 513351:

Table 10.1-1 Sample Receipt from 513351

Samples Received	Immunogenicity Sample Numbers	Date Received	Sample Condition
Pretreatment and Day 22	20	01-Oct-2020	Frozen
Day 43	10	27-Oct-2020	Frozen
Day 74	10	24-Nov-2020	Frozen

Samples were received from Charles River Laboratories, Edinburgh. All samples were stored in a freezer set to -80°C at the Test Site.

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11 AMENDMENTS AND DEVIATIONS

11.1 Amendments

No amendments to the phase plan were issued during phase 2020-AZD1222-0217.

11.2 Deviations

No deviations to the phase plan were issued during phase 2020-AZD1222-0217.

12 IMMUNOGENICITY RESULTS

12.1 Calibration Curve and Quality Control Data

The standard curves for reported data were acceptable over the validated ranges. Data for the calibration standards were acceptable for all assays reported with full data presented in Table 16.1-1 and a representative curve presented in Section 16.2. The inter-assay accuracy for calibration standards within limits of quantification ranged from -6.8 to 3.6% RE with precision ≤ 5.8% CV.

Data for QC samples are presented in Table 16.3-1. The inter-assay accuracy for batch acceptance QC samples ranged from -19.3 to 0.3% RE with precision ≤ 15.6% CV indicating acceptable performance during the study.

12.2 Immunogenicity Sample Results

A total of 40 serum samples were analysed on 3 analytical runs. The Fate of Run Summary is presented in Table 15.1-1.

Immunogenicity data for study 513351 are presented in Table 12.2-1.

All samples were analysed in duplicate with immunogenicity results reported in AU/mL to three decimal places.

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Table 12.2-1 Immunogenicity in Mouse Serum Samples from Study 513351 (AU/mL)

STUDY	ANIMAL NUMBER	GROUP	SEX	TIMEPOINT	STUDY DAY	CONCENTRATION (AU/mL)
513351	2201	Gp2M	Male	Pretreatment	1	<0.250
513351	2201	Gp2M	Male	Day 22	22	269.436
513351	2201	Gp2M	Male	Day 43	43	744.020
513351	2201	Gp2M	Male	Day 74	74	1166.157
513351	2202	Gp2M	Male	Pretreatment	1	<0.250
513351	2202	Gp2M	Male	Day 22	22	437.818
513351	2202	Gp2M	Male	Day 43	43	1029.032
513351	2202	Gp2M	Male	Day 74	74	1219.516
513351	2203	Gp2M	Male	Pretreatment	1	<0.250
513351	2203	Gp2M	Male	Day 22	22	278.852
513351	2203	Gp2M	Male	Day 43	43	829.283
513351	2203	Gp2M	Male	Day 74	74	1362.400
513351	2204	Gp2M	Male	Pretreatment	1	<0.250
513351	2204	Gp2M	Male	Day 22	22	24.297
513351	2204	Gp2M	Male	Day 43	43	69.734
513351	2204	Gp2M	Male	Day 74	74	60.586
513351	2205	Gp2M	Male	Pretreatment	1	<0.250
513351	2205	Gp2M	Male	Day 22	22	851.620
513351	2205	Gp2M	Male	Day 43	43	2297.104
513351	2205	Gp2M	Male	Day 74	74	2392.740
513351	2701	Gp2F	Female	Pretreatment	1	<0.250
513351	2701	Gp2F	Female	Day 22	22	1309.884
513351	2701	Gp2F	Female	Day 43	43	2759.980
513351	2701	Gp2F	Female	Day 74	74	5115.546
513351	2702	Gp2F	Female	Pretreatment	1	<0.250
513351	2702	Gp2F	Female	Day 22	22	358.910
513351	2702	Gp2F	Female	Day 43	43	569.779
513351	2702	Gp2F	Female	Day 74	74	596.055
513351	2703	Gp2F	Female	Pretreatment	1	<0.250
513351	2703	Gp2F	Female	Day 22	22	1243.263
513351	2703	Gp2F	Female	Day 43	43	1933.017
513351	2703	Gp2F	Female	Day 74	74	2538.552
513351	2704	Gp2F	Female	Pretreatment	1	<0.250
513351	2704	Gp2F	Female	Day 22	22	61.889
513351	2704	Gp2F	Female	Day 43	43	233.627
513351	2704	Gp2F	Female	Day 74	74	247.947
513351	2705	Gp2F	Female	Pretreatment	1	<0.250
513351	2705	Gp2F	Female	Day 22	22	1107.705

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Table 12.2-1 Immunogenicity in Mouse Serum Samples from Study 513351 (AU/mL)

STUDY	ANIMAL NUMBER	GROUP	SEX	TIMEPOINT	STUDY DAY	CONCENTRATION (AU/mL)
513351	2705	Gp2F	Female	Day 43	43	2684.628
513351	2705	Gp2F	Female	Day 74	74	3888.503

<0.250; sample presented a result at MRD below limit of quantification

13 CONCLUSION

The bioanalysis for the relative quantitative detection of IgG antibodies against SARS-CoV-2 spike protein in murine serum was evaluated in samples originating from Study 513351.

Data for the calibration standards and QC samples through the phase met *a priori* acceptance criteria indicating reproducible performance.

Data for pre-treatment samples from all animals were negative for IgG against the SARS-CoV-2 spike protein. Following administration of AZD1222 all animals demonstrated sero-conversion with measurable levels of IgG at Day 22 sustained through Day 43 and Day 74.

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14 APPENDIX 1: ASSAY PROCEDURE

14.1 Reagent Preparation

14.1.1 Preparation of Capture Reagent (SARS-CoV-2 Trimeric Spike Protein)

The capture reagent was diluted to 3.0 µg/mL in DPBS. Capture reagent was prepared immediately prior to use.

14.1.2 Preparation of Detection Reagent

The detection reagent (SULFO-TAG labelled goat anti-mouse antibody) stock was diluted to 1.0 µg/mL in assay diluent (Blocker Casein in PBS). Detection reagent was prepared immediately prior to use.

14.1.3 Preparation of 0.1% Tween 20 in PBS Wash Buffer

2 L of 0.1% Tween 20 in PBS Wash Buffer was made from 20 PBS Tablets, plus 2.0 mL Tween 20 in 2 L lab grade water (volumes were scaled as required). The expiry date was one week from date of preparation.

14.1.4 Preparation of 1% Matrix

Pooled mouse serum (100% matrix) was diluted to 1% matrix in assay diluent (Blocker Casein in PBS).

14.1.5 Preparation of Read Buffer B

MSD Gold Read Buffer B was used neat as supplied.

14.2 Preparation of Samples and Controls

All samples and controls were subject to the 100-fold MRD in assay diluent (Blocker Casein in PBS) prior to analysis.

Where required, samples underwent further dilution in 1% murine serum, as detailed in Section 9.7.

Appendix 13

Test Site Identifier: 2020-AZD1222-0217
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14.3 Assay Procedure – Example Blank Proforma

Procedure		Performed by: Initial/date
1.	Coat MSD 96 well high bind plate with 25 µL per well of Trimer at 3 µg/mL in DPBS. Seal the plate and incubate overnight at 2-8°C.	Step 1
2.	Wash the plate 3x with 300 µL per well of Wash Buffer and blot dry. Block plate with 150 µL per well of Blocker Casein in PBS, seal the plate and incubate for at least 30 minutes on a plate shaker set at 25°C and shaking at 700 rpm. Incubation Start Time:_____ Incubation End Time:_____ Total Incubation Time:_____ Shaker ID:_____ Washer ID:	Steps 2 to 5
3.	Wash the plate 3x with 300 µL per well of Wash Buffer and blot dry. Add 50 µL per well of calibration or QC/test sample to the plate. Seal the plate and incubate on a plate shaker set at 25°C and shaking at 700 rpm for 120 ± 10 minutes. Incubation Start Time:_____ Incubation End Time:_____ Total Incubation Time:_____ Shaker ID:_____ Washer ID:_____	
4.	Wash the plate 3x with 300 µL per well of Wash Buffer and blot dry. Add 50 µL per well of Detection Reagent. Seal the plate and incubate on a plate shaker set at 25°C and shaking at 700 rpm for 60 ± 5 minutes. Incubation Start Time:_____ Incubation End Time:_____ Total Incubation Time:_____ Shaker ID: Washer ID:	
5.	Wash the plate 3x with 150 µL per well of Wash Buffer and blot dry. Add 150 µL per well of Read Buffer B and read on MSD S 600 within 10 minutes. Time Read Buffer added:_____ Time Plate Read:_____ Total Time:_____ Washer ID:_____	

Appendix 13
Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

15 APPENDIX 2: RUN ACCEPTANCE AND SAMPLE REPEATS

15.1 2020-AZD1222-0217 Run Summary

The Fate of Run Summary performed under this bioanalytical phase report is detailed in Table 15.1-1.

Table 15.1-1 2020-AZD1222-0217 Run Summary

Run ID	Date	Assay outcome (Pass / Fail)
Run 1	25-Nov-2020	Pass
Run 2	25-Nov-2020	Pass
Run 3	26-Nov-2020	Pass

15.2 Analytical Repeats

15.2.1 Batch Repeats

All analytical runs met acceptance criteria and no run repeats were performed.

15.2.2 Sample Repeats

No individual samples required repeat during 2020-AZD1222-0217.

Appendix 13

Test Site Identifier: 2020-AZD1222-0217
Study Number: 513351

16 APPENDIX 3: CALIBRATION STANDARD AND QUALITY CONTROL DATA

16.1 Calibration Curve Data

Table 16.1-1 Calibration Curve Data

Run ID	Sample ID	Std 1	Std 2	Std 3	Std 4	Std 5	Std 6	Std 7	Std 8	Std 9	Std 10	Std 11
	Nominal Conc. (ng/mL)	**128,000**	**64,000**	**32,000**	**16,000**	**8,000**	**4,000**	**2,000**	**1,000**	**500**	**250**	**125**
Run 1	Replicate 1 (ng/mL)	175963	64655	31248	16956	8285	4183	2033	1024	451	255	134
	Replicate 2 (ng/mL)	107789	62345	29964	14798	8042	3999	1980	1041	453	271	127
	Mean (ng/mL)	141876	63500	30606	15877	8163	4091	2006	1033	452	263	130
	% CV	34.0	2.6	3.0	9.6	2.1	3.2	1.9	1.2	0.3	4.3	4.0
	% RE	10.8	-0.8	-4.4	-0.8	2.0	2.3	0.3	3.3	-9.6	5.2	4.3
Run 2	Replicate 1 (ng/mL)	174330	59492	29735	15700	8082	4210	2050	958	471	254	138
	Replicate 2 (ng/mL)	125633	61683	31496	15555	8086	4201	2068	1037	459	252	119
	Mean (ng/mL)	149981	60588	30615	15627	8084	4206	2059	997	465	253	128
	% CV	23.0	2.6	4.1	0.7	0.0	0.1	0.6	5.6	1.8	0.6	10.2
	% RE	17.2	-5.3	-4.3	-2.3	1.0	5.1	2.9	-0.3	-7.0	1.3	2.6
Run 3	Replicate 1 (ng/mL)	147903	68739	31927	16482	8547	4495	2159	1041	499	260	137
	Replicate 2 (ng/mL)	117347	60972	29779	14864	7566	3776	1954	940	461	241	115
	Mean (ng/mL)	132625	64856	30853	15673	8056	4135	2056	991	480	250	126
	% CV	16.3	8.5	4.9	7.3	8.6	12.3	7.0	7.2	5.6	5.3	12.5
	% RE	3.6	1.3	-3.6	-2.0	0.7	3.4	2.8	-0.9	-3.9	0.1	0.5
Overall Inter-assay statistics	Mean (ng/mL)	141494	62981	30691	15726	8101	4144	2041	1007	466	256	128
	Std Dev	29251.0	3294.1	975.9	862.3	323.3	240.2	72.2	45.7	18.0	9.8	9.7
	% CV	20.7	5.2	3.2	5.5	4.0	5.8	3.5	4.5	3.9	3.9	7.5
	% RE	10.5	-1.6	-4.1	-1.7	1.3	3.6	2.0	0.7	-6.8	2.2	2.5

Appendix 13

Test Site Identifier: 2020-AZD1222-0217
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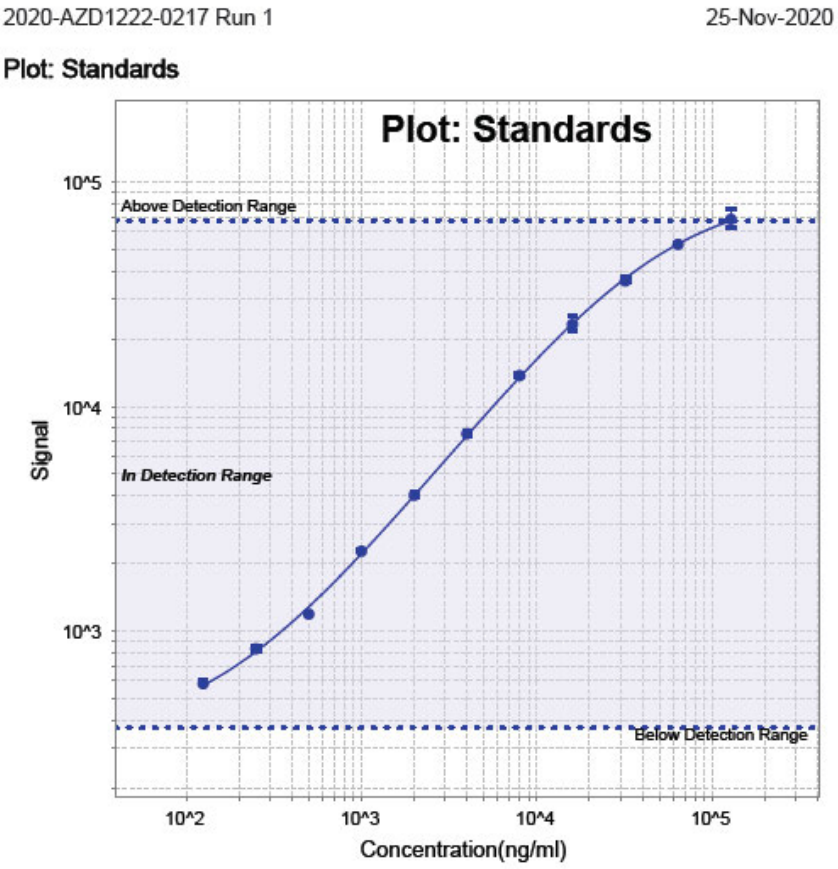
16.2 Representative Calibration Curve – 2020-AZD1222-0217 Run 1



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Test Site Identifier: 2020-AZD1222-0217
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16.3 Quality Control Data

Table 16.3-1 Quality Control Data

Run ID	Sample ID	HQC		MQC		LQC	
	Nominal Conc. (ng/mL)	24000		3000		625	
Run 1	Replicate 1 (ng/mL)	21755	20467	3124	3129	655	672
	Replicate 2 (ng/mL)	22041	17209	2766	2621	675	489
	Mean (ng/mL)	21898	18838	2945	2875	665	580
	% CV	0.9	12.2	8.6	12.5	2.1	22.3
	% RE	-8.8	-21.5	-1.8	-4.2	6.4	-7.1
Run 2	Replicate 1 (ng/mL)	28861	20188	3309	3134	695	629
	Replicate 2 (ng/mL)	25515	21818	3161	2799	647	555
	Mean (ng/mL)	27188	21003	3235	2966	671	592
	% CV	8.7	5.5	3.2	8.0	5.1	8.8
	% RE	13.3	-12.5	7.8	-1.1	7.4	-5.3
Run 3	Replicate 1 (ng/mL)	20997	18941	2856	2753	587	629
	Replicate 2 (ng/mL)	18868	17649	2586	2561	503	457
	Mean (ng/mL)	19932	18295	2721	2657	545	543
	% CV	7.6	5.0	7.0	5.1	10.9	22.5
	% RE	-16.9	-23.8	-9.3	-11.4	-12.8	-13.1
Overall Inter-assay statistics	Mean (ng/mL)	23006	19379	2967	2833	627	572
	Std Dev	3584.1	1770.9	274.6	246.8	70.8	85.9
	% CV	15.6	9.1	9.3	8.7	11.3	15.0
	% RE	-4.1	-19.3	-1.1	-5.6	0.3	-8.5

Appendix 14

Individual organ weights

Explanation page

Abbreviation	Description
AVS	Aberrant value suppressed/excluded from mean/statistical calculations
Body Wt or BW	Body weight
Exc	Excluded from relative, mean/statistical calculations
LIBW	Lungs infused before weighing
MPE	Macroscopic pathology – excluded from mean/statistical calculations
MPI	Macroscopic pathology – included in mean/statistical calculations
NT	Not taken
OA	Omitted activity
ONP	Organ not present for weighing
OPOP	Only one of the paired organs present for weighing
Organ Weight (BW)	Organ weight relative to body weight
RC	Result comment
X	Excluded (applied with one of the exclusion flags)

Note: This is a comprehensive list of abbreviations. All of the abbreviations listed may not be applicable to this report.

Dosing information

Dosing information is abbreviated on various data outputs; the following represents the dosing information for this study:

Group no.	Dose volume[a] (µL)	Total viral particle (VP)/dose	Viral particle (VP) concentration per 1 mL
1	70	0	0
2	70	3.7×10^{10}	5.3 x10^11

[a] 35 µL was administered in the thigh muscle of each hind limb on each dosing occasion (total dose volume = 0.07 mL)

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
1001	35.3	0.515	0.140	0.0063	0.0016	0.080	0.242
1002	41.7	0.506	0.118	0.0067	0.0034	0.023	0.251
1003	36.6	0.488	0.098	0.0060	0.0025	0.022	0.253
1004	36.4	0.532	0.101	0.0083	0.0024	0.016	0.231
1005	36.9	0.495	0.124	0.0069	0.0019	0.020	0.250
1006	37.4 [a]	0.519	0.094	0.0049	0.0014	0.024	0.231
1007	35.3	0.495	0.119	0.0081	0.0036	0.030	0.204
1008	35.8 [a]	0.486	0.114	0.0114	0.0016	0.015	0.196
1009	36.3	0.502	0.114	0.0040	0.0030	0.024	0.190
1010	38.0	0.504	0.134	0.0034	0.0027	0.065	0.228
1011	36.4 [a]	0.548	0.086	0.0076	0.0035	0.021	0.266
1012	39.3	0.491	0.111	0.0085	0.0021	0.018	0.246
1013	36.3 [a]	0.558	0.119	0.0074	0.0019	0.019	0.259
1014	42.1	0.512	0.121	0.0055	0.0021	0.025	0.235
1015	37.1	0.494	0.104	0.0082	0.0026	0.023	0.231
1016	35.6	0.508	0.114	0.0070	0.0020	0.018	0.207

[a] [RC:Weight Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
1001	0.663	2.147	0.274	0.088	0.318	0.030
1002	0.747	2.449	0.334	0.121	0.263	0.032
1003	0.709	2.211	0.462	0.085	0.259	0.030
1004	0.770	2.178	0.235	0.083	0.216	0.026
1005	0.730	2.216	0.244	0.069	0.282	0.027
1006	0.637	2.321	0.259	0.078	0.254	0.028
1007	0.659	2.219	0.230	0.092	0.274	0.030
1008	0.669	2.199	0.226	0.104	0.224	0.024
1009	0.791	2.170	0.210	0.075	0.275	0.038
1010	0.651	2.384	0.221	0.102	0.257	0.037
1011	0.873	2.249	0.233	0.082	0.245	0.021
1012	0.714	2.288	0.233	0.098	0.282	0.026
1013	0.690	2.164	0.229	0.086	0.313	0.047
1014	0.650	2.511	0.256	0.083	0.263	0.021
1015	0.648	2.111	0.216	0.095	0.206	0.028
1016	0.699	2.156	0.232	0.086	0.291	0.041

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
1017	39.7	0.501	0.125	0.0094	0.0030	0.054	0.226
1018	33.4 [a]	0.501	0.099	0.0041	0.0034	0.014	0.273
1019	41.0	0.527	0.121	0.0040	0.0023	0.027	0.226
1020	37.3	0.519	0.122	0.0093	0.0022	0.020	0.205
Mean	37.40	0.5101	0.1139	0.00685	0.00246	0.0279	0.2325
SD	2.28	0.0194	0.0135	0.00211	0.00067	0.0175	0.0233
N	20	20	20	20	20	20	20

[a] [RC:Weight Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
1017	0.683	2.129	0.238	0.096	0.327	0.033
1018	0.708	1.899	0.225	0.107	0.186	0.031
1019	0.639	2.327	0.266	0.094	0.300	0.031
1020	0.687	2.049	0.258	0.095	0.306	0.029
Mean	0.7009	2.2189	0.2541	0.0910	0.2671	0.0305
SD	0.0591	0.1378	0.0560	0.0121	0.0381	0.0064
N	20	20	20	20	20	20

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
2001	36.1	0.471	0.093	0.0060	0.0030	0.026	0.204
2002	38.4	0.550	0.128	0.0086	0.0031	0.019	0.214
2003	38.9	0.502	0.116	0.0061	0.0018	0.021	0.234
2004	36.0	0.514	0.097	0.0063	0.0035	0.022	0.249
2005	35.8	0.502	0.119	0.0057	0.0018	0.053	0.241
2006	40.4	0.530	0.118	0.0072	0.0021	0.026	0.219
2007	38.4	0.496	0.100	0.0063	0.0032	0.107	0.200
2008	40.5	0.509	0.099	0.0029	0.0029	0.012	0.221
2009	38.4	0.455	0.112	0.0046	0.0019	0.038	0.215
2010	42.0	0.524	0.116	0.0035	0.0030	0.024	0.236
2011	39.2	0.536	0.111	0.0052	0.0020	0.028	0.253
2012	43.0	0.540	0.129	0.0081	0.0031	0.049	0.239
2013	39.8	0.526	0.116	0.0100	0.0028	0.038	0.217
2014	38.9	0.509	0.135	0.0070	0.0032	0.017	0.192
2015	43.4	0.525	0.137	0.0077	0.0028	0.026	0.216
2016	34.5 [a]	0.518	0.135	0.0072	0.0034	0.034	0.207

[a] [RC:Weight Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
2001	0.693	2.358	0.211	0.121	0.224	0.041
2002	0.709	2.801	0.233	0.106	0.344	0.029
2003	0.743	2.390	0.236	0.093	0.280	0.038
2004	0.690	2.366	0.261	0.126	0.269	0.028
2005	0.646	2.179	0.236	0.079	0.296	0.036
2006	0.765	2.680	0.231	0.141	0.261	0.054
2007	0.721	2.118	0.232	0.089	0.210	0.031
2008	0.663	2.460	0.201	0.133	0.246	0.043
2009	0.703	2.262	0.221	0.128	0.279	0.036
2010	0.720	2.602	0.228	0.111	0.265	0.035
2011	0.814	2.632	0.217	0.145	0.219	0.035
2012	0.838	2.817	0.257	0.153	0.276	0.041
2013	0.690	2.323	0.231	0.141	0.265	0.035
2014	0.635	2.268	0.217	0.113	0.264	0.028
2015	0.829	2.663	0.238	0.145	0.328	0.040
2016	0.688	2.065	0.225	0.118	0.315	0.021

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
2017	36.4	0.478	0.123	0.0072	0.0021	0.028	0.193
2018	38.9	0.512	0.102	0.0074	0.0019	0.026	0.198
2019	39.6 [a]	0.456	0.146	0.0075	0.0024	0.034	0.224
2020	41.6	0.525	0.136	0.0070	0.0036	0.041	0.253
Mean	39.01	0.5089	0.1184	0.00658	0.00268	0.0335	0.2213
SD	2.43	0.0265	0.0152	0.00167	0.00062	0.0202	0.0194
N	20	20	20	20	20	20	20
%Diff	4.32	-0.2255	3.9508	-4.01460	8.94309	19.8925	-4.8387

[a] [RC:Weight Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
2017	0.755	2.234	0.205	0.121	0.283	0.026
2018	0.713	2.490	0.251	0.104	0.233	0.034
2019	0.723	2.000	0.244	0.123	0.270	0.025
2020	0.682	2.724	0.291	0.140	0.341	0.022
Mean	0.7210	2.4216	0.2333	0.1215	0.2734	0.0339
SD	0.0561	0.2469	0.0208	0.0203	0.0378	0.0080
N	20	20	20	20	20	20
%Diff	2.8751	9.1376	-8.1677	33.5899	2.3778	11.1475

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
1501	33.3	0.517	0.0075	0.0033	0.210	0.456	2.190
1502	30.4	0.525	0.0101	0.0028	0.170	0.378	1.864
1503	29.9	0.514	0.0060	0.0029	0.153	0.449	1.590
1504	31.3	0.511	0.0100	0.0033	0.169	0.448	1.726
1505	34.7	0.476	0.0131	0.0042	0.228	0.443	2.331
1506	26.2	0.508	0.0103	0.0032	0.157	0.353	1.620
1507	32.6	0.522	0.0070	0.0039	0.183	0.409	1.944
1508	29.8	0.455	0.0112	0.0018	0.178	0.383	1.766
1509	28.3	0.487	0.0136	0.0026	0.166	0.410	1.481
1510	29.0	0.552	0.0072	0.0032	0.159	0.382	1.741
1511	30.0	0.536	0.0095	0.0034	0.165	0.450	1.723
1512	27.4	0.401	0.0087	0.0030	0.162	0.380	1.730
1513	31.6 [a]	0.538	0.0126	0.0041	0.166	0.432	2.058
1514	26.7	0.486	0.0124	0.0023	0.149	0.386	1.500
1515	30.7	0.473	0.0065	0.0037	0.175	0.445	1.835
1516	28.4	0.508	0.0098	0.0022	0.187	0.391	1.720

[a] [RC:Weight Verified]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
1501	0.246	0.008	0.159	0.045	0.153
1502	0.196	0.028	0.133	0.050	0.112
1503	0.196	0.023	0.115	0.037	0.307
1504	0.230	0.031	0.166	0.077	0.378
1505	0.212	0.030	0.157	0.070	0.154
1506	0.182	0.019	0.091	0.045	0.193
1507	0.221	0.018	0.124	0.051	0.295
1508	0.233	0.012	0.118	0.036	0.307
1509	0.199	0.047	0.141	0.045	0.461
1510	0.191	0.028	0.099	0.036	0.324
1511	0.198	0.030	0.156	0.025	0.192
1512	0.188	0.023	0.120	0.036	0.210
1513	0.238	0.035	0.129	0.037	0.166
1514	0.180	0.014	0.091	0.045	0.285
1515	0.190	0.028	0.157	0.042	0.263
1516	0.193	0.018	0.101	0.046	0.140

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
1517	30.1	0.531	0.0128	0.0033	0.194	0.459	1.955
1518	29.8	0.508	0.0120	0.0031	0.161	0.397	1.521
1519	28.7	0.502	0.0084	0.0035	0.163	0.403	1.628
1520	25.0 [a]	0.455	0.0086	0.0017	0.148	0.341	1.294
Mean	29.70	0.5003	0.00987	0.00308	0.1722	0.4098	1.7609
SD	2.39	0.0354	0.00236	0.00069	0.0202	0.0359	0.2491
N	20	20	20	20	20	20	20

[a] [RC:Weight Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
1517	0.208	0.024	0.116	0.038	0.248
1518	0.197	0.015	0.098	0.047	0.275
1519	0.220	0.017	0.105	0.035	0.267
1520	0.187	0.025	0.077	0.018	0.289
Mean	0.2053	0.0237	0.1227	0.0431	0.2510
SD	0.0197	0.0090	0.0265	0.0132	0.0870
N	20	20	20	20	20

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
2501	33.9	0.519	0.0094	0.0037	0.187	0.516	2.358
2502	32.5	0.505	0.0065	0.0032	0.176	0.497	2.461
2503	27.3	0.520	0.0086	0.0024	0.170	0.381	1.464
2504	34.0	0.514	0.0094	0.0037	0.208	0.470	2.157
2505	33.3	0.501	0.0160	0.0029	0.184	0.534	2.420
2506	28.8 [a]	0.493	0.0093	0.0030	0.177	0.485	1.841
2507	29.8	0.468	0.0095	0.0021	0.171	0.362	2.047
2508	27.0	0.498	0.0132	0.0016	0.191	0.401	1.635
2509	29.1	0.481	0.0139	0.0029	0.176	0.385	1.624
2510	29.5	0.525	0.0115	0.0028	0.174	0.395	1.898
2511	27.8	0.519	0.0106	0.0027	0.182	0.371	1.636
2512	32.6 [a]	0.511	0.0080	0.0026	0.200	0.531	2.302
2513	28.9 [a]	0.498	0.0104	0.0025	0.161	0.420	1.651
2514	29.5 [b]	0.473	0.0101	0.0026	0.175	0.403	1.579
2515	29.8	0.498	0.0124	0.0024	0.157	0.457	1.999
2516	29.9	0.490	0.0097	0.0025	0.171	0.415	1.711

[a] [RC:Weight Verified.]
[b] [RC:Weigtht Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
2501	0.229	0.034	0.207	0.054	0.161
2502	0.200	0.027	0.266	0.057	0.170
2503	0.187	0.026	0.107	0.022	0.169
2504	0.237	0.033	0.249	0.033	0.216
2505	0.229	0.031	0.191	0.046	0.183
2506	0.182	0.025	0.121	0.029	0.156
2507	0.190	0.020	0.135	0.067	0.131
2508	0.205	0.013	0.148	0.025	0.188
2509	0.203	0.034	0.193	0.042	0.180
2510	0.242	0.022	0.157	0.052	0.297
2511	0.198	0.024	0.175	0.047	0.198
2512	0.213	0.032	0.262	0.041	0.167
2513	0.215	0.023	0.134	0.034	0.224
2514	0.241	0.024	0.140	0.029	0.206
2515	0.209	0.027	0.153	0.041	0.184
2516	0.229	0.020	0.138	0.046	0.173

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
2517	27.4 [a]	0.488	0.0095	0.0028	0.168	0.350	1.522
2518	32.6	0.533	0.0152	0.0032	0.180	0.457	1.990
2519	35.1 [b]	0.489	0.0156	0.0026	0.190	0.450	1.694
2520	29.9 [b]	0.512	0.0103	0.0030	0.157	0.395	1.445
Mean	30.44	0.5018	0.01096	0.00276	0.1778	0.4338	1.8717
SD	2.47	0.0175	0.00262	0.00049	0.0132	0.0573	0.3284
N	20	20	20	20	20	20	20
%Diff	2.49	0.2999	11.04916	-10.24390	3.2530	5.8572	6.2953

[a] [RC:Weight Verified,]
[b] [RC:Weight Verified.]

Appendix 15

Individual absolute organ weights: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
2517	0.208	0.022	0.145	0.046	0.233
2518	0.240	0.031	0.226	0.056	0.365
2519	0.244	0.028	0.184	0.032	0.393
2520	0.192	0.026	0.144	0.045	0.381
Mean	0.2147	0.0261	0.1738	0.0422	0.2188
SD	0.0203	0.0054	0.0472	0.0118	0.0776
N	20	20	20	20	20
%Diff	4.5798	10.3594	41.6633	-1.9744	-12.8312

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
1101	38.1	0.539	0.109	0.0041	0.0028	0.025	0.227
1102	39.0	0.528	0.114	0.0033	0.0028	0.038	0.225
1103	39.0	0.493	0.114	0.0046	0.0031	0.011	0.198
1104	40.7	0.494	0.120	0.0105	0.0021	0.023	0.229
1105	36.7	0.506	0.116	0.0068	0.0011	0.020	0.217
1106	42.4	0.525	0.105	0.0105	0.0032	0.020	0.258
1107	38.7	0.531	0.114	0.0063	0.0030	0.017	0.221
1108	41.5	0.468	0.110	0.0046	0.0027	0.022	0.202
1109	40.4	0.499	0.102	0.0025	0.0027	0.030	0.186
1110	41.1	0.543	0.134	0.0072	0.0018	0.062	0.284
1111	40.3	0.522	0.105	0.0065	0.0025	0.022	0.217
1112	54.0	0.534	0.157	0.0065	0.0027	0.023	0.249
1113	46.3	0.508	0.164	0.0066	0.0028	0.060	0.243
1114	41.8 [a]	0.499	0.127	0.0033	0.0024	0.026	0.244
1115	44.2	0.494	0.135	0.0037	0.0029	0.015	0.213
1116	40.5	0.542	0.123	0.0063	0.0028	0.017	0.231

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
1101	0.745	2.384	0.234	0.091	0.224	0.005
1102	0.500	2.331	0.224	0.079	0.218	0.019
1103	0.600	1.980	0.210	0.076	0.227	0.019
1104	0.724	2.631	0.251	0.078	0.257	0.024
1105	0.502	2.277	0.223	0.093	0.256	0.028
1106	0.710	2.812	0.251	0.110	0.281	0.021
1107	0.754	2.249	0.234	0.110	0.235	0.024
1108	0.550	2.288	0.255	0.095	0.257	0.022
1109	0.684	2.397	0.217	0.099	0.245	0.044
1110	0.793	2.352	0.193	0.142	0.317	0.043
1111	0.705	2.349	0.245	0.098	0.275	0.019
1112	0.802	3.607	0.238	0.112	0.353	0.048
1113	0.764	2.572	0.228	0.097	0.264	0.063
1114	0.730	2.563	0.247	0.136	0.354	0.038
1115	0.624	2.563	0.244	0.093	0.285	0.026
1116	0.735	2.444	0.238	0.095	0.271	0.032

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
1117	40.3	0.489	0.132	0.0057	0.0029	0.039	0.232
1118	39.7	0.513	0.111	0.0060	0.0030	0.020	0.208
1119	44.4	0.463	0.131	0.0040	0.0029	0.016	0.227
1120	42.2	0.533	0.110	0.0054	0.0028	0.026	0.258
Mean	41.57	0.5112	0.1217	0.00572	0.00265	0.0266	0.2285
SD	3.70	0.0237	0.0167	0.00213	0.00049	0.0137	0.0231
N	20	20	20	20	20	20	20

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
1117	0.672	2.295	0.229	0.117	0.253	0.050
1118	0.702	2.212	0.248	0.125	0.249	0.034
1119	0.793	2.373	0.235	0.110	0.246	0.033
1120	0.818	2.232	0.434	0.079	0.271	0.022
Mean	0.6954	2.4456	0.2439	0.1018	0.2669	0.0307
SD	0.0950	0.3273	0.0473	0.0186	0.0375	0.0137
N	20	20	20	20	20	20

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
2101	41.0	0.508	0.131	0.0030	0.0031	0.013	0.233
2102	37.1	0.504	0.118	0.0030	0.0023	0.030	0.251
2103	41.7	0.560	0.116	0.0067	0.0044	0.035	0.271
2104	40.3	0.521	0.102	0.0075	0.0021	0.014	0.256
2105	37.9	0.513	0.142	0.0094	0.0018	0.014	0.246
2106	38.2	0.559	0.108	0.0070	0.0027	0.014	0.228
2107	40.6	0.507	0.109	0.0050	0.0029	0.042	0.241
2108	40.6	0.518	0.112	0.0037	0.0022	0.012	0.245
2109	42.3	0.513	0.127	0.0040	0.0028	0.016	0.231
2110	37.4	0.543	0.103	0.0055	0.0022	0.024	0.217
2111	38.6	0.514	0.132	0.0045	0.0025	0.071	0.224
2112	40.6	0.554	0.119	0.0045	0.0029	0.038	0.264
2113	38.5	0.498	0.106	0.0036	0.0029	0.023	0.215
2114	37.4	0.482	0.130	0.0042	0.0025	0.038	0.240
2115	38.4 [a]	0.495	0.108	0.0054	0.0007	0.008	0.233
2116	39.7	0.518	0.101	0.0045	0.0029	0.011	0.214

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
2101	0.789	2.209	0.246	0.083	0.252	0.043
2102	0.671	2.164	0.307	0.083	0.254	0.028
2103	0.904	2.484	0.267	0.113	0.310	0.013
2104	0.777	2.176	0.209	0.079	0.231	0.025
2105	0.712	2.535	0.197	0.080	0.284	0.029
2106	0.829	2.122	0.241	0.105	0.264	0.021
2107	0.748	2.344	0.255	0.103	0.275	0.039
2108	0.854	2.450	0.234	0.092	0.290	0.029
2109	0.814	2.490	0.233	0.090	0.357	0.019
2110	0.923	2.282	0.246	0.088	0.279	0.022
2111	0.726	2.277	0.283	0.145	0.272	0.037
2112	0.662	2.516	0.271	0.104	0.305	0.032
2113	0.680	2.187	0.253	0.117	0.268	0.021
2114	0.751	2.519	0.229	0.091	0.302	0.014
2115	0.476	2.132	0.240	0.086	0.267	0.035
2116	0.792	2.236	0.243	0.086	0.225	0.034

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Epididymis (g)	Gland Adrenal (g)	Gland Pituitary (g)	Gland Prostate (g)	Heart (g)
	-	-	-	-	-	-	-
2117	39.1	0.504	0.130	0.0080	0.0030	0.045	0.254
2118	43.3 [a]	0.477	0.138	0.0055	0.0029	0.012	0.218
2119	35.7 [a]	0.503	0.092	0.0018	0.0026	0.031	0.213
2120	39.5	0.530	0.116	0.0097	0.0038	0.025	0.233
Mean	39.40	0.5161	0.1170	0.00533	0.00266	0.0258	0.2364
SD	1.92	0.0232	0.0138	0.00213	0.00074	0.0157	0.0171
N	20	20	20	20	20	20	20
%Diff	-5.22	0.9586	-3.8224	-6.90559	0.37736	-3.0075	3.4581

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)					
	Kidney (g)	Liver/ Gallbladder (g)	Lung (g)	Spleen (g)	Testis (g)	Thymus (g)
	-	-	-	-	-	-
2117	0.686	2.406	0.221	0.126	0.311	0.039
2118	0.705	2.209	0.240	0.096	0.302	0.034
2119	0.612	1.962	0.212	0.103	0.180	0.035
2120	0.837	2.342	0.273	0.107	0.256	0.013
Mean	0.7474	2.3021	0.2450	0.0989	0.2742	0.0281
SD	0.1045	0.1621	0.0264	0.0169	0.0377	0.0092
N	20	20	20	20	20	20
%Diff	7.4854	-5.8658	0.4510	-2.8501	2.7351	-8.4691

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
1601	37.0	0.539	0.0087	0.0045	0.177	0.491	2.426
1602	26.7	0.439	0.0090	0.0026	0.144	0.347	1.498
1603	30.0 [a]	0.502	0.0090	0.0034	0.158	0.416	1.570
1604	31.5 [a]	0.560	0.0105	0.0039	0.192	0.437	1.632
1605	30.5	0.502	0.0075	0.0017	0.144	0.412	1.895
1606	28.1	0.475	0.0335	0.0043	0.156	0.370	1.749
1607	28.9	0.490	0.0071	0.0030	0.189	0.492	1.863
1608	32.6	0.500	0.0105	0.0042	0.205	0.447	2.053
1609	28.1 [a]	0.552	0.0077	0.0028	0.231	0.371	1.435
1610	32.2	0.524	0.0068	0.0040	0.159	0.412	1.923
1611	31.6	0.573	0.0107	0.0024	0.215	0.406	1.983
1612	32.8 [a]	0.486	0.0085	0.0038	0.159	0.425	1.925
1613	36.5	0.536	0.0117	0.0032	0.183	0.480	1.989
1614	36.4	0.535	0.0095	0.0044	0.170	0.391	2.172
1615	26.5 [a]	0.485	0.0102	0.0021	0.142	0.297	1.266
1616	36.8	0.539	0.0113	0.0050	0.197	0.459	2.334

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
1601	0.220	NT	0.156	0.018	0.142
1602	0.152	0.016	0.089	0.051	0.245
1603	0.184	0.026	0.118	0.035	0.167
1604	0.206	0.026	0.117	0.037	0.509
1605	0.201	0.024	0.137	0.034	0.158
1606	0.178	0.031	0.121	0.060	0.268
1607	0.201	0.029	0.162	0.036	0.171
1608	0.205	0.037	0.139	0.079	0.211
1609	0.126	0.031	0.079	0.036	0.275
1610	0.214	0.026	0.152	0.033	0.327
1611	0.230	0.030	0.157	0.049	0.389
1612	0.185	0.025	0.137	0.035	0.450
1613	0.241	0.030	0.143	0.036	0.210
1614	0.209	0.030	0.142	0.029	0.132
1615	0.166	0.012	0.102	0.037	0.299
1616	0.221	0.031	0.152	0.049	0.307

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
1617	34.5	0.537	0.0050	0.0030	0.166	0.454	1.823
1619	31.0	0.533	0.0085	0.0040	0.196	0.382	1.565
1620	32.7 [a]	0.533	0.0060	0.0033	0.175	0.398	1.940
Mean	31.81	0.5179	0.01009	0.00345	0.1767	0.4151	1.8443
SD	3.34	0.0334	0.00595	0.00089	0.0251	0.0503	0.3004
N	19	19	19	19	19	19	19

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
1617	0.220	0.019	0.108	0.022	0.146
1619	0.220	0.025	0.154	0.054	0.541
1620	0.234	0.027	0.131	0.042	0.149
Mean	0.2007	0.0264	0.1314	0.0406	0.2682
SD	0.0294	0.0060	0.0240	0.0140	0.1266
N	19	18	19	19	19

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
2601	33.2	0.539	0.0086	0.0029	0.200	0.538	2.257
2602	34.1	0.536	0.0095	0.0032	0.182	0.465	1.980
2603	35.2	0.527	0.0125	0.0038	0.192	0.480	2.152
2604	27.9	0.498	0.0105	0.0022	0.160	0.433	1.738
2605	26.7	0.512	0.0144	0.0030	0.165	0.382	1.466
2606	31.4	0.496	0.0085	0.0036	0.151	0.449	1.894
2607	29.3	0.474	0.0096	0.0034	0.145	0.393	1.664
2608	37.2 [a]	0.556	0.0082	0.0047	0.180	0.430	1.751
2609	31.8 [a]	0.514	0.0080	0.0037	0.152	0.457	1.637
2610	39.3	0.566	0.0085	0.0038	0.204	0.528	2.717
2611	30.5 [a]	0.536	0.0109	0.0039	0.189	0.413	1.678
2612	28.9	0.530	0.0055	0.0025	0.170	0.411	1.386
2613	25.8	0.503	0.0042	0.0023	0.162	0.317	1.332
2614	32.6	0.526	0.0083	0.0038	0.167	0.423	2.024
2615	27.3 [a]	0.439	0.0030	0.0038	0.152	0.346	1.447
2616	30.0	0.511	0.0135	0.0029	0.209	0.391	1.599

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
2601	0.263	0.023	0.116	0.021	0.242
2602	0.267	0.042	0.140	0.059	0.347
2603	0.229	0.029	0.157	0.024	0.162
2604	0.187	0.012	0.081	0.021	0.128
2605	0.245	0.022	0.128	0.043	0.247
2606	0.229	0.017	0.118	0.028	0.181
2607	0.187	0.011	0.142	0.041	0.150
2608	0.233	0.043	0.124	0.028	0.314
2609	0.195	0.023	0.120	0.024	0.360
2610	0.221	0.044	0.186	0.042	0.190
2611	0.224	0.034	0.121	0.030	0.277
2612	0.202	0.020	0.121	0.039	0.424
2613	0.153	0.018	0.115	0.029	0.439
2614	0.195	0.021	0.147	0.038	0.145
2615	0.159	0.018	0.079	0.016	0.237
2616	0.199	0.017	0.128	0.020	0.290

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2		Organ Weight (Absolute)					
	Terminal Body Wt (g)	Brain (g)	Gland Adrenal (g)	Gland Pituitary (g)	Heart (g)	Kidney (g)	Liver/ Gallbladder (g)
	-	-	-	-	-	-	-
2617	25.1 [a]	0.480	0.0059	0.0027	0.142	0.282	1.142
2618	29.6 [a]	0.506	0.0094	0.0009	0.189	0.418	1.380
2619	26.5 [a]	0.552	0.0125	0.0028	0.170	0.344	1.214
2620	32.2	0.510	0.0099	0.0040	0.171	0.463	1.921
Mean	30.73	0.5156	0.00907	0.00320	0.1726	0.4182	1.7190
SD	3.82	0.0301	0.00295	0.00084	0.0199	0.0647	0.3862
N	20	20	20	20	20	20	20
%Diff	-3.40	-0.4527	-10.10433	-7.46189	-2.3407	0.7335	-6.7948

[a] [RC:Value Confirmed]

Appendix 15

Individual absolute organ weights: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (Absolute)				
	Lung (g)	Ovary (g)	Spleen (g)	Thymus (g)	Uterus/Cervix/Oviduct (g)
	-	-	-	-	-
2617	0.173	0.017	0.094	0.024	0.107
2618	0.280	0.019	0.106	0.025	0.351
2619	0.194	0.014	0.100	0.045	0.234
2620	0.228	0.027	0.163	0.037	0.148
Mean	0.2132	0.0236	0.1243	0.0317	0.2487
SD	0.0348	0.0100	0.0266	0.0108	0.0993
N	20	20	20	20	20
%Diff	6.2116	-10.7579	-5.3806	-21.9819	-7.2930

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
1001	1.4589	0.3966	0.0178	0.0045	0.2266	0.6856	1.8782
1002	1.2134	0.2830	0.0161	0.0082	0.0552	0.6019	1.7914
1003	1.3333	0.2678	0.0164	0.0068	0.0601	0.6913	1.9372
1004	1.4615	0.2775	0.0228	0.0066	0.0440	0.6346	2.1154
1005	1.3415	0.3360	0.0187	0.0051	0.0542	0.6775	1.9783
1006	1.3877	0.2513	0.0131	0.0037	0.0642	0.6176	1.7032
1007	1.4023	0.3371	0.0229	0.0102	0.0850	0.5779	1.8669
1008	1.3575	0.3184	0.0318	0.0045	0.0419	0.5475	1.8687
1009	1.3829	0.3140	0.0110	0.0083	0.0661	0.5234	2.1791
1010	1.3263	0.3526	0.0089	0.0071	0.1711	0.6000	1.7132
1011	1.5055	0.2363	0.0209	0.0096	0.0577	0.7308	2.3984
1012	1.2494	0.2824	0.0216	0.0053	0.0458	0.6260	1.8168
1013	1.5372	0.3278	0.0204	0.0052	0.0523	0.7135	1.9008
1014	1.2162	0.2874	0.0131	0.0050	0.0594	0.5582	1.5439
1015	1.3315	0.2803	0.0221	0.0070	0.0620	0.6226	1.7466
1016	1.4270	0.3202	0.0197	0.0056	0.0506	0.5815	1.9635

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
1001	6.0822	0.7762	0.2493	0.9008	0.0850
1002	5.8729	0.8010	0.2902	0.6307	0.0767
1003	6.0410	1.2623	0.2322	0.7077	0.0820
1004	5.9835	0.6456	0.2280	0.5934	0.0714
1005	6.0054	0.6612	0.1870	0.7642	0.0732
1006	6.2059	0.6925	0.2086	0.6791	0.0749
1007	6.2861	0.6516	0.2606	0.7762	0.0850
1008	6.1425	0.6313	0.2905	0.6257	0.0670
1009	5.9780	0.5785	0.2066	0.7576	0.1047
1010	6.2737	0.5816	0.2684	0.6763	0.0974
1011	6.1786	0.6401	0.2253	0.6731	0.0577
1012	5.8219	0.5929	0.2494	0.7176	0.0662
1013	5.9614	0.6309	0.2369	0.8623	0.1295
1014	5.9644	0.6081	0.1971	0.6247	0.0499
1015	5.6900	0.5822	0.2561	0.5553	0.0755
1016	6.0562	0.6517	0.2416	0.8174	0.1152

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
1017	1.2620	0.3149	0.0237	0.0076	0.1360	0.5693	1.7204
1018	1.5000	0.2964	0.0123	0.0102	0.0419	0.8174	2.1198
1019	1.2854	0.2951	0.0098	0.0056	0.0659	0.5512	1.5585
1020	1.3914	0.3271	0.0249	0.0059	0.0536	0.5496	1.8418
Mean	1.36854	0.30512	0.01840	0.00660	0.07467	0.62386	1.88210
SD	0.09513	0.03705	0.00585	0.00191	0.04793	0.07514	0.20819
N	20	20	20	20	20	20	20

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
1017	5.3627	0.5995	0.2418	0.8237	0.0831
1018	5.6856	0.6737	0.3204	0.5569	0.0928
1019	5.6756	0.6488	0.2293	0.7317	0.0756
1020	5.4933	0.6917	0.2547	0.8204	0.0777
Mean	5.93804	0.68006	0.24370	0.71473	0.08202
SD	0.25137	0.14913	0.03279	0.10027	0.01879
N	20	20	20	20	20

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
2001	1.3047	0.2576	0.0166	0.0083	0.0720	0.5651	1.9197
2002	1.4323	0.3333	0.0224	0.0081	0.0495	0.5573	1.8464
2003	1.2905	0.2982	0.0157	0.0046	0.0540	0.6015	1.9100
2004	1.4278	0.2694	0.0175	0.0097	0.0611	0.6917	1.9167
2005	1.4022	0.3324	0.0159	0.0050	0.1480	0.6732	1.8045
2006	1.3119	0.2921	0.0178	0.0052	0.0644	0.5421	1.8936
2007	1.2917	0.2604	0.0164	0.0083	0.2786	0.5208	1.8776
2008	1.2568	0.2444	0.0072	0.0072	0.0296	0.5457	1.6370
2009	1.1849	0.2917	0.0120	0.0049	0.0990	0.5599	1.8307
2010	1.2476	0.2762	0.0083	0.0071	0.0571	0.5619	1.7143
2011	1.3673	0.2832	0.0133	0.0051	0.0714	0.6454	2.0765
2012	1.2558	0.3000	0.0188	0.0072	0.1140	0.5558	1.9488
2013	1.3216	0.2915	0.0251	0.0070	0.0955	0.5452	1.7337
2014	1.3085	0.3470	0.0180	0.0082	0.0437	0.4936	1.6324
2015	1.2097	0.3157	0.0177	0.0065	0.0599	0.4977	1.9101
2016	1.5014	0.3913	0.0209	0.0099	0.0986	0.6000	1.9942

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
2001	6.5319	0.5845	0.3352	0.6205	0.1136
2002	7.2943	0.6068	0.2760	0.8958	0.0755
2003	6.1440	0.6067	0.2391	0.7198	0.0977
2004	6.5722	0.7250	0.3500	0.7472	0.0778
2005	6.0866	0.6592	0.2207	0.8268	0.1006
2006	6.6337	0.5718	0.3490	0.6460	0.1337
2007	5.5156	0.6042	0.2318	0.5469	0.0807
2008	6.0741	0.4963	0.3284	0.6074	0.1062
2009	5.8906	0.5755	0.3333	0.7266	0.0938
2010	6.1952	0.5429	0.2643	0.6310	0.0833
2011	6.7143	0.5536	0.3699	0.5587	0.0893
2012	6.5512	0.5977	0.3558	0.6419	0.0953
2013	5.8367	0.5804	0.3543	0.6658	0.0879
2014	5.8303	0.5578	0.2905	0.6787	0.0720
2015	6.1359	0.5484	0.3341	0.7558	0.0922
2016	5.9855	0.6522	0.3420	0.9130	0.0609

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
2017	1.3132	0.3379	0.0198	0.0058	0.0769	0.5302	2.0742
2018	1.3162	0.2622	0.0190	0.0049	0.0668	0.5090	1.8329
2019	1.1515	0.3687	0.0189	0.0061	0.0859	0.5657	1.8258
2020	1.2620	0.3269	0.0168	0.0087	0.0986	0.6082	1.6394
Mean	1.30788	0.30401	0.01691	0.00689	0.08623	0.56850	1.85092
SD	0.08612	0.03933	0.00427	0.00166	0.05287	0.05419	0.13051
N	20	20	20	20	20	20	20
%Diff	-4.43258	-0.36389	-8.09912	4.31479	15.47502	-8.87482	-1.65649

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
2017	6.1374	0.5632	0.3324	0.7775	0.0714
2018	6.4010	0.6452	0.2674	0.5990	0.0874
2019	5.0505	0.6162	0.3106	0.6818	0.0631
2020	6.5481	0.6995	0.3365	0.8197	0.0529
Mean	6.20645	0.59935	0.31106	0.70299	0.08676
SD	0.48247	0.05533	0.04568	0.10462	0.01899
N	20	20	20	20	20
%Diff	4.52019	-11.86839	27.64470	-1.64311	5.78071

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
1501	1.5526	0.0225	0.0099	0.6306	1.3694	6.5766	0.7387
1502	1.7270	0.0332	0.0092	0.5592	1.2434	6.1316	0.6447
1503	1.7191	0.0201	0.0097	0.5117	1.5017	5.3177	0.6555
1504	1.6326	0.0319	0.0105	0.5399	1.4313	5.5144	0.7348
1505	1.3718	0.0378	0.0121	0.6571	1.2767	6.7176	0.6110
1506	1.9389	0.0393	0.0122	0.5992	1.3473	6.1832	0.6947
1507	1.6012	0.0215	0.0120	0.5613	1.2546	5.9632	0.6779
1508	1.5268	0.0376	0.0060	0.5973	1.2852	5.9262	0.7819
1509	1.7208	0.0481	0.0092	0.5866	1.4488	5.2332	0.7032
1510	1.9034	0.0248	0.0110	0.5483	1.3172	6.0034	0.6586
1511	1.7867	0.0317	0.0113	0.5500	1.5000	5.7433	0.6600
1512	1.4635	0.0318	0.0109	0.5912	1.3869	6.3139	0.6861
1513	1.7025	0.0399	0.0130	0.5253	1.3671	6.5127	0.7532
1514	1.8202	0.0464	0.0086	0.5581	1.4457	5.6180	0.6742
1515	1.5407	0.0212	0.0121	0.5700	1.4495	5.9772	0.6189
1516	1.7887	0.0345	0.0077	0.6585	1.3768	6.0563	0.6796

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
1501	0.0240	0.4775	0.1351	0.4595
1502	0.0921	0.4375	0.1645	0.3684
1503	0.0769	0.3846	0.1237	1.0268
1504	0.0990	0.5304	0.2460	1.2077
1505	0.0865	0.4524	0.2017	0.4438
1506	0.0725	0.3473	0.1718	0.7366
1507	0.0552	0.3804	0.1564	0.9049
1508	0.0403	0.3960	0.1208	1.0302
1509	0.1661	0.4982	0.1590	1.6290
1510	0.0966	0.3414	0.1241	1.1172
1511	0.1000	0.5200	0.0833	0.6400
1512	0.0839	0.4380	0.1314	0.7664
1513	0.1108	0.4082	0.1171	0.5253
1514	0.0524	0.3408	0.1685	1.0674
1515	0.0912	0.5114	0.1368	0.8567
1516	0.0634	0.3556	0.1620	0.4930

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
1517	1.7641	0.0425	0.0110	0.6445	1.5249	6.4950	0.6910
1518	1.7047	0.0403	0.0104	0.5403	1.3322	5.1040	0.6611
1519	1.7491	0.0293	0.0122	0.5679	1.4042	5.6725	0.7666
1520	1.8200	0.0344	0.0068	0.5920	1.3640	5.1760	0.7480
Mean	1.69173	0.03343	0.01030	0.57946	1.38134	5.91180	0.69198
SD	0.14591	0.00833	0.00190	0.04233	0.08246	0.48393	0.04809
N	20	20	20	20	20	20	20

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
1517	0.0797	0.3854	0.1262	0.8239
1518	0.0503	0.3289	0.1577	0.9228
1519	0.0592	0.3659	0.1220	0.9303
1520	0.1000	0.3080	0.0720	1.1560
Mean	0.08001	0.41039	0.14401	0.85530
SD	0.03066	0.06890	0.03869	0.31389
N	20	20	20	20

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
2501	1.5310	0.0277	0.0109	0.5516	1.5221	6.9558	0.6755
2502	1.5538	0.0200	0.0098	0.5415	1.5292	7.5723	0.6154
2503	1.9048	0.0315	0.0088	0.6227	1.3956	5.3626	0.6850
2504	1.5118	0.0276	0.0109	0.6118	1.3824	6.3441	0.6971
2505	1.5045	0.0480	0.0087	0.5526	1.6036	7.2673	0.6877
2506	1.7118	0.0323	0.0104	0.6146	1.6840	6.3924	0.6319
2507	1.5705	0.0319	0.0070	0.5738	1.2148	6.8691	0.6376
2508	1.8444	0.0489	0.0059	0.7074	1.4852	6.0556	0.7593
2509	1.6529	0.0478	0.0100	0.6048	1.3230	5.5808	0.6976
2510	1.7797	0.0390	0.0095	0.5898	1.3390	6.4339	0.8203
2511	1.8669	0.0381	0.0097	0.6547	1.3345	5.8849	0.7122
2512	1.5675	0.0245	0.0080	0.6135	1.6288	7.0613	0.6534
2513	1.7232	0.0360	0.0087	0.5571	1.4533	5.7128	0.7439
2514	1.6034	0.0342	0.0088	0.5932	1.3661	5.3525	0.8169
2515	1.6711	0.0416	0.0081	0.5268	1.5336	6.7081	0.7013
2516	1.6388	0.0324	0.0084	0.5719	1.3880	5.7224	0.7659

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
2501	0.1003	0.6106	0.1593	0.4749
2502	0.0831	0.8185	0.1754	0.5231
2503	0.0952	0.3919	0.0806	0.6190
2504	0.0971	0.7324	0.0971	0.6353
2505	0.0931	0.5736	0.1381	0.5495
2506	0.0868	0.4201	0.1007	0.5417
2507	0.0671	0.4530	0.2248	0.4396
2508	0.0481	0.5481	0.0926	0.6963
2509	0.1168	0.6632	0.1443	0.6186
2510	0.0746	0.5322	0.1763	1.0068
2511	0.0863	0.6295	0.1691	0.7122
2512	0.0982	0.8037	0.1258	0.5123
2513	0.0796	0.4637	0.1176	0.7751
2514	0.0814	0.4746	0.0983	0.6983
2515	0.0906	0.5134	0.1376	0.6174
2516	0.0669	0.4615	0.1538	0.5786

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
2517	1.7810	0.0347	0.0102	0.6131	1.2774	5.5547	0.7591
2518	1.6350	0.0466	0.0098	0.5521	1.4018	6.1043	0.7362
2519	1.3932	0.0444	0.0074	0.5413	1.2821	4.8262	0.6952
2520	1.7124	0.0344	0.0100	0.5251	1.3211	4.8328	0.6421
Mean	1.65788	0.03609	0.00905	0.58598	1.42328	6.12969	0.70668
SD	0.13403	0.00819	0.00132	0.04589	0.12737	0.78222	0.05814
N	20	20	20	20	20	20	20
%Diff	-2.00084	7.96044	-12.09317	1.12561	3.03575	3.68576	2.12504

Appendix 16

Individual organ weights relative to body weight: main study animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
2517	0.0803	0.5292	0.1679	0.8504
2518	0.0951	0.6933	0.1718	1.1196
2519	0.0798	0.5242	0.0912	1.1197
2520	0.0870	0.4816	0.1505	1.2742
Mean	0.08536	0.56592	0.13864	0.71813
SD	0.01467	0.12315	0.03773	0.23726
N	20	20	20	20
%Diff	6.69143	37.89718	-3.73430	-16.03707

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
1101	1.4147	0.2861	0.0108	0.0073	0.0656	0.5958	1.9554
1102	1.3538	0.2923	0.0085	0.0072	0.0974	0.5769	1.2821
1103	1.2641	0.2923	0.0118	0.0079	0.0282	0.5077	1.5385
1104	1.2138	0.2948	0.0258	0.0052	0.0565	0.5627	1.7789
1105	1.3787	0.3161	0.0185	0.0030	0.0545	0.5913	1.3678
1106	1.2382	0.2476	0.0248	0.0075	0.0472	0.6085	1.6745
1107	1.3721	0.2946	0.0163	0.0078	0.0439	0.5711	1.9483
1108	1.1277	0.2651	0.0111	0.0065	0.0530	0.4867	1.3253
1109	1.2351	0.2525	0.0062	0.0067	0.0743	0.4604	1.6931
1110	1.3212	0.3260	0.0175	0.0044	0.1509	0.6910	1.9294
1111	1.2953	0.2605	0.0161	0.0062	0.0546	0.5385	1.7494
1112	0.9889	0.2907	0.0120	0.0050	0.0426	0.4611	1.4852
1113	1.0972	0.3542	0.0143	0.0060	0.1296	0.5248	1.6501
1114	1.1938	0.3038	0.0079	0.0057	0.0622	0.5837	1.7464
1115	1.1176	0.3054	0.0084	0.0066	0.0339	0.4819	1.4118
1116	1.3383	0.3037	0.0156	0.0069	0.0420	0.5704	1.8148

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
1101	6.2572	0.6142	0.2388	0.5879	0.0131
1102	5.9769	0.5744	0.2026	0.5590	0.0487
1103	5.0769	0.5385	0.1949	0.5821	0.0487
1104	6.4644	0.6167	0.1916	0.6314	0.0590
1105	6.2044	0.6076	0.2534	0.6975	0.0763
1106	6.6321	0.5920	0.2594	0.6627	0.0495
1107	5.8114	0.6047	0.2842	0.6072	0.0620
1108	5.5133	0.6145	0.2289	0.6193	0.0530
1109	5.9332	0.5371	0.2450	0.6064	0.1089
1110	5.7226	0.4696	0.3455	0.7713	0.1046
1111	5.8288	0.6079	0.2432	0.6824	0.0471
1112	6.6796	0.4407	0.2074	0.6537	0.0889
1113	5.5551	0.4924	0.2095	0.5702	0.1361
1114	6.1316	0.5909	0.3254	0.8469	0.0909
1115	5.7986	0.5520	0.2104	0.6448	0.0588
1116	6.0346	0.5877	0.2346	0.6691	0.0790

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
1117	1.2134	0.3275	0.0141	0.0072	0.0968	0.5757	1.6675
1118	1.2922	0.2796	0.0151	0.0076	0.0504	0.5239	1.7683
1119	1.0428	0.2950	0.0090	0.0065	0.0360	0.5113	1.7860
1120	1.2630	0.2607	0.0128	0.0066	0.0616	0.6114	1.9384
Mean	1.23810	0.29244	0.01382	0.00639	0.06406	0.55174	1.67556
SD	0.11624	0.02692	0.00521	0.00124	0.03186	0.05788	0.21094
N	20	20	20	20	20	20	20

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
1117	5.6948	0.5682	0.2903	0.6278	0.1241
1118	5.5718	0.6247	0.3149	0.6272	0.0856
1119	5.3446	0.5293	0.2477	0.5541	0.0743
1120	5.2891	1.0284	0.1872	0.6422	0.0521
Mean	5.87604	0.58957	0.24575	0.64216	0.07305
SD	0.43419	0.11557	0.04593	0.07054	0.02991
N	20	20	20	20	20

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
2101	1.2390	0.3195	0.0073	0.0076	0.0317	0.5683	1.9244
2102	1.3585	0.3181	0.0081	0.0062	0.0809	0.6765	1.8086
2103	1.3429	0.2782	0.0161	0.0106	0.0839	0.6499	2.1679
2104	1.2928	0.2531	0.0186	0.0052	0.0347	0.6352	1.9280
2105	1.3536	0.3747	0.0248	0.0047	0.0369	0.6491	1.8786
2106	1.4634	0.2827	0.0183	0.0071	0.0366	0.5969	2.1702
2107	1.2488	0.2685	0.0123	0.0071	0.1034	0.5936	1.8424
2108	1.2759	0.2759	0.0091	0.0054	0.0296	0.6034	2.1034
2109	1.2128	0.3002	0.0095	0.0066	0.0378	0.5461	1.9243
2110	1.4519	0.2754	0.0147	0.0059	0.0642	0.5802	2.4679
2111	1.3316	0.3420	0.0117	0.0065	0.1839	0.5803	1.8808
2112	1.3645	0.2931	0.0111	0.0071	0.0936	0.6502	1.6305
2113	1.2935	0.2753	0.0094	0.0075	0.0597	0.5584	1.7662
2114	1.2888	0.3476	0.0112	0.0067	0.1016	0.6417	2.0080
2115	1.2891	0.2813	0.0141	0.0018	0.0208	0.6068	1.2396
2116	1.3048	0.2544	0.0113	0.0073	0.0277	0.5390	1.9950

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
2101	5.3878	0.6000	0.2024	0.6146	0.1049
2102	5.8329	0.8275	0.2237	0.6846	0.0755
2103	5.9568	0.6403	0.2710	0.7434	0.0312
2104	5.3995	0.5186	0.1960	0.5732	0.0620
2105	6.6887	0.5198	0.2111	0.7493	0.0765
2106	5.5550	0.6309	0.2749	0.6911	0.0550
2107	5.7734	0.6281	0.2537	0.6773	0.0961
2108	6.0345	0.5764	0.2266	0.7143	0.0714
2109	5.8865	0.5508	0.2128	0.8440	0.0449
2110	6.1016	0.6578	0.2353	0.7460	0.0588
2111	5.8990	0.7332	0.3756	0.7047	0.0959
2112	6.1970	0.6675	0.2562	0.7512	0.0788
2113	5.6805	0.6571	0.3039	0.6961	0.0545
2114	6.7353	0.6123	0.2433	0.8075	0.0374
2115	5.5521	0.6250	0.2240	0.6953	0.0911
2116	5.6322	0.6121	0.2166	0.5668	0.0856

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Epididymis (%)	Gland Adrenal (%)	Gland Pituitary (%)	Gland Prostate (%)	Heart (%)	Kidney (%)
	-	-	-	-	-	-	-
2117	1.2890	0.3325	0.0205	0.0077	0.1151	0.6496	1.7545
2118	1.1016	0.3187	0.0127	0.0067	0.0277	0.5035	1.6282
2119	1.4090	0.2577	0.0050	0.0073	0.0868	0.5966	1.7143
2120	1.3418	0.2937	0.0246	0.0096	0.0633	0.5899	2.1190
Mean	1.31265	0.29712	0.01351	0.00673	0.06601	0.60077	1.89759
SD	0.08203	0.03373	0.00547	0.00177	0.04087	0.04495	0.25627
N	20	20	20	20	20	20	20
%Diff	6.02166	1.60226	-2.24380	5.27988	3.04503	8.88711	13.25162

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Male Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)				
	Liver/ Gallbladder (%)	Lung (%)	Spleen (%)	Testis (%)	Thymus (%)
	-	-	-	-	-
2117	6.1535	0.5652	0.3223	0.7954	0.0997
2118	5.1016	0.5543	0.2217	0.6975	0.0785
2119	5.4958	0.5938	0.2885	0.5042	0.0980
2120	5.9291	0.6911	0.2709	0.6481	0.0329
Mean	5.84964	0.62309	0.25152	0.69523	0.07145
SD	0.40901	0.07325	0.04534	0.08374	0.02332
N	20	20	20	20	20
%Diff	-0.44932	5.68407	2.34819	8.26391	-2.18999

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
1601	1.4568	0.0235	0.0122	0.4784	1.3270	6.5568	0.5946
1602	1.6442	0.0337	0.0097	0.5393	1.2996	5.6105	0.5693
1603	1.6733	0.0300	0.0113	0.5267	1.3867	5.2333	0.6133
1604	1.7778	0.0333	0.0124	0.6095	1.3873	5.1810	0.6540
1605	1.6459	0.0246	0.0056	0.4721	1.3508	6.2131	0.6590
1606	1.6904	0.1192	0.0153	0.5552	1.3167	6.2242	0.6335
1607	1.6955	0.0246	0.0104	0.6540	1.7024	6.4464	0.6955
1608	1.5337	0.0322	0.0129	0.6288	1.3712	6.2975	0.6288
1609	1.9644	0.0274	0.0100	0.8221	1.3203	5.1068	0.4484
1610	1.6273	0.0211	0.0124	0.4938	1.2795	5.9720	0.6646
1611	1.8133	0.0339	0.0076	0.6804	1.2848	6.2753	0.7278
1612	1.4817	0.0259	0.0116	0.4848	1.2957	5.8689	0.5640
1613	1.4685	0.0321	0.0088	0.5014	1.3151	5.4493	0.6603
1614	1.4698	0.0261	0.0121	0.4670	1.0742	5.9670	0.5742
1615	1.8302	0.0385	0.0079	0.5358	1.1208	4.7774	0.6264
1616	1.4647	0.0307	0.0136	0.5353	1.2473	6.3424	0.6005

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
1601	-	0.4216	0.0486	0.3838
1602	0.0599	0.3333	0.1910	0.9176
1603	0.0867	0.3933	0.1167	0.5567
1604	0.0825	0.3714	0.1175	1.6159
1605	0.0787	0.4492	0.1115	0.5180
1606	0.1103	0.4306	0.2135	0.9537
1607	0.1003	0.5606	0.1246	0.5917
1608	0.1135	0.4264	0.2423	0.6472
1609	0.1103	0.2811	0.1281	0.9786
1610	0.0807	0.4720	0.1025	1.0155
1611	0.0949	0.4968	0.1551	1.2310
1612	0.0762	0.4177	0.1067	1.3720
1613	0.0822	0.3918	0.0986	0.5753
1614	0.0824	0.3901	0.0797	0.3626
1615	0.0453	0.3849	0.1396	1.1283
1616	0.0842	0.4130	0.1332	0.8342

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
1617	1.5565	0.0145	0.0087	0.4812	1.3159	5.2841	0.6377
1619	1.7194	0.0274	0.0129	0.6323	1.2323	5.0484	0.7097
1620	1.6300	0.0183	0.0101	0.5352	1.2171	5.9327	0.7156
Mean	1.63912	0.03248	0.01081	0.55964	1.30762	5.77827	0.63038
SD	0.14333	0.02181	0.00240	0.09144	0.12551	0.54774	0.06570
N	19	19	19	19	19	19	19

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 1	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
1617	0.0551	0.3130	0.0638	0.4232
1619	0.0806	0.4968	0.1742	1.7452
1620	0.0826	0.4006	0.1284	0.4557
Mean	0.08370	0.41286	0.13029	0.85823
SD	0.01829	0.06623	0.04861	0.41588
N	18	19	19	19

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
2601	1.6235	0.0259	0.0087	0.6024	1.6205	6.7982	0.7922
2602	1.5718	0.0279	0.0094	0.5337	1.3636	5.8065	0.7830
2603	1.4972	0.0355	0.0108	0.5455	1.3636	6.1136	0.6506
2604	1.7849	0.0376	0.0079	0.5735	1.5520	6.2294	0.6703
2605	1.9176	0.0539	0.0112	0.6180	1.4307	5.4906	0.9176
2606	1.5796	0.0271	0.0115	0.4809	1.4299	6.0318	0.7293
2607	1.6177	0.0328	0.0116	0.4949	1.3413	5.6792	0.6382
2608	1.4946	0.0220	0.0126	0.4839	1.1559	4.7070	0.6263
2609	1.6164	0.0252	0.0116	0.4780	1.4371	5.1478	0.6132
2610	1.4402	0.0216	0.0097	0.5191	1.3435	6.9135	0.5623
2611	1.7574	0.0357	0.0128	0.6197	1.3541	5.5016	0.7344
2612	1.8339	0.0190	0.0087	0.5882	1.4221	4.7958	0.6990
2613	1.9496	0.0163	0.0089	0.6279	1.2287	5.1628	0.5930
2614	1.6135	0.0255	0.0117	0.5123	1.2975	6.2086	0.5982
2615	1.6081	0.0110	0.0139	0.5568	1.2674	5.3004	0.5824
2616	1.7033	0.0450	0.0097	0.6967	1.3033	5.3300	0.6633

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
2601	0.0693	0.3494	0.0633	0.7289
2602	0.1232	0.4106	0.1730	1.0176
2603	0.0824	0.4460	0.0682	0.4602
2604	0.0430	0.2903	0.0753	0.4588
2605	0.0824	0.4794	0.1610	0.9251
2606	0.0541	0.3758	0.0892	0.5764
2607	0.0375	0.4846	0.1399	0.5119
2608	0.1156	0.3333	0.0753	0.8441
2609	0.0723	0.3774	0.0755	1.1321
2610	0.1120	0.4733	0.1069	0.4835
2611	0.1115	0.3967	0.0984	0.9082
2612	0.0692	0.4187	0.1349	1.4671
2613	0.0698	0.4457	0.1124	1.7016
2614	0.0644	0.4509	0.1166	0.4448
2615	0.0659	0.2894	0.0586	0.8681
2616	0.0567	0.4267	0.0667	0.9667

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)						
	Brain (%)	Gland Adrenal (%)	Gland Pituitary (%)	Heart (%)	Kidney (%)	Liver/ Gallbladder (%)	Lung (%)
	-	-	-	-	-	-	-
2617	1.9124	0.0235	0.0108	0.5657	1.1235	4.5498	0.6892
2618	1.7095	0.0318	0.0030	0.6385	1.4122	4.6622	0.9459
2619	2.0830	0.0472	0.0106	0.6415	1.2981	4.5811	0.7321
2620	1.5839	0.0307	0.0124	0.5311	1.4379	5.9658	0.7081
Mean	1.69490	0.02976	0.01037	0.56541	1.35915	5.54879	0.69643
SD	0.17172	0.01062	0.00234	0.06239	0.11881	0.70906	0.10318
N	20	20	20	20	20	20	20
%Diff	3.40310	-8.36642	-4.05385	1.03021	3.94142	-3.97138	10.47829

Appendix 16

Individual organ weights relative to body weight: recovery animals

513351

Sex: Female Day(s) Relative to Start Date

70 ul Group 2	Organ Weight (BW)			
	Ovary (%)	Spleen (%)	Thymus (%)	Uterus/Cervix/Oviduct (%)
	-	-	-	-
2617	0.0677	0.3745	0.0956	0.4263
2618	0.0642	0.3581	0.0845	1.1858
2619	0.0528	0.3774	0.1698	0.8830
2620	0.0839	0.5062	0.1149	0.4596
Mean	0.07489	0.40322	0.10399	0.82249
SD	0.02407	0.06206	0.03592	0.36089
N	20	20	20	20
%Diff	-10.52328	-2.33583	-20.18511	-4.16382

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1001	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; unilateral, focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1002	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

BONE MARROW, STERNUM : Hematopoietic cells, increased; diffuse, mild
GLAND, SALIVARY, PAROTID : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LIVER : Hypertrophy; centrilobular, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, MAMMARY - Not Present In Section.
GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1003	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

LUNG : Abnormal consistency : (Comment) spongy, all lobes (TGL) [LUNG : Congestion; agonal, diffuse, mild (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

HEART : Infiltration, mononuclear cell; perivascular, focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
LUNG : Congestion; agonal, diffuse, mild [LUNG : Abnormal consistency : (Comment) spongy, all lobes (G)]
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, MAMMARY - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1004	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : Cyst; pars distalis
LYMPH NODE, INGUINAL : (Comment) tissue sampled is adipose
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GALT - Not Present In Section.
LYMPH NODE, INGUINAL - Not Present In Wet Tissues.

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Individual macroscopic and microscopic pathology

513351

Animal:	1005	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LUNG : Aggregate; focal, minimal, macrophage : (Comment) subpleural
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) cervical, thoracic and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1006	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Ectopia; thymic
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, MAMMARY - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1007	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

BRAIN : Accumulation, adipocyte; focal, minimal, choroid plexus : (Comment) 4th ventricle
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : (Comment) no DRG in lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, MAMMARY - Not Present In Section.
URETER - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1008	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) underlying muscle, red (TGL) [SITE, ADMINISTRATION, 2 : Congestion; focal, minimal, subcutaneous tissue (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PROSTATE : Infiltration, mononuclear cell; interstitial, focal, minimal
GLAND, SALIVARY, PAROTID : Infiltration, mononuclear cell; interstitial, focal, minimal
HEART : Infiltration, mononuclear cell; perivascular, focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
NERVE, OPTIC : (Note) One Of A Pair Available For Evaluation.
PANCREAS : Infiltration, mononuclear cell; focal, minimal, adipose tissue
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Congestion; focal, minimal, subcutaneous tissue [SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) underlying muscle, red (G)]
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SEMINAL VESICLE; GLAND, THYROID; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, MAMMARY - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1009	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : (Note) One Of A Pair Available For Evaluation.
GLAND, SALIVARY, PAROTID : Infiltration, mononuclear cell; perivascular, focal, minimal
NERVE, OPTIC : (Note) One Of A Pair Available For Evaluation.
PANCREAS : Infiltration, mononuclear cell; perivascular, focal, minimal, adipose tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; SITE, ADMINISTRATION, 1; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1010	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Cortex And One Medulla Available For Evaluation.
GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, THYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Cyst; tubular, focal, minimal
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1011	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

LUNG : Focus, dark : (Comment) red, few, all lobes, up to 2mm diam (TGL)
LUNG : Focus, pale : (Comment) few, all lobes, pinpoint (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1012	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1013	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1014	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1015	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1016	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1017	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1018	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1019	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1020	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1501	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Cortex And One Medulla Available For Evaluation.
GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal, follicle
LYMPH NODE, MANDIBULAR : (Comment) sample is salivary gland
OVARY : (Note) One Of A Pair Available For Evaluation.
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, MANDIBULAR - Not Present In Wet Tissues.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1502	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Cortex And One Medulla Available For Evaluation.
KIDNEY : Basophilia; tubular, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1503	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1504	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Comment) pars nervosa not available for examination
KIDNEY : Infiltration, mononuclear cell; perivascular, focal, minimal, pelvis
LIVER : Inflammation, mononuclear cell; focal, minimal
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1505	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, SALIVARY, MANDIBULAR : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Infiltration, mononuclear cell; perivascular, focal, minimal, pelvis
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
PANCREAS : Infiltration, mononuclear cell; focal, minimal, adipose tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic and lumbar sections
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; SITE, ADMINISTRATION, 1; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1506	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal, follicle
KIDNEY : Infiltration, mononuclear cell; perivascular, focal, minimal, pelvis
KIDNEY : Basophilia; tubular, focal, minimal
KIDNEY : Cyst; tubular, focal, minimal
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) cervical section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1507	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1508	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, THYROID : Ectopia; thymic
KIDNEY : Infiltration, mononuclear cell; perivascular, focal, minimal, pelvis
KIDNEY : Basophilia; tubular, focal, minimal
LUNG : Metaplasia; osseous, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1509	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, THYROID : (Note) One Of A Pair Available For Evaluation.
LUNG : Aggregate; focal, minimal, macrophage
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
URETER : (Comment) samples are adipose tissue

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.
URETER - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1510	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GALT - Not Present In Wet Tissues.
GLAND, PITUITARY - Not Present In Wet Tissues.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1511	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1512	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1513	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1514	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

OVARY : Cyst, clear : (Comment) one, left, 5mm diam (TGL)
SKIN : Thin hair coat : (Comment) muzzle (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1515	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1516	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1517	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1518	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1519	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1520	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2001	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, THYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LYMPH NODE, INGUINAL : (Comment) left sample is adipose tissue
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic and lumbar sections
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE, FEMUR; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

BONE MARROW, STERNUM - Not Present In Wet Tissues.
BONE, STERNUM - Not Present In Section.
GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2002	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) red, muscle (TGL) [SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

EYE : (Comment) second eye too damaged to evaluate
EYE : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Ectopia; thymic
HEART : Infiltration, mononuclear cell; focal, minimal, ventricular free wall
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
LIVER : Infiltration, mononuclear cell; perivascular, focal, minimal
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue [SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) red, muscle (G)]
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2003	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2004	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PROSTATE : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
LYMPH NODE, INGUINAL : (Comment) left sample is adipose tissue; right sample is muscle
NERVE, SCIATIC : Infiltration, mononuclear cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, INGUINAL - Not Present In Wet Tissues.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2005	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
NERVE, SCIATIC : Infiltration, mononuclear cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2006	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, THYROID : Cyst; focal, minimal, follicle
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, MAMMARY - Not Present In Wet Tissues.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2007	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Infiltration, mononuclear cell; focal, minimal, pelvis
NERVE, SCIATIC : Infiltration, mononuclear cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2008	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Infiltration, mononuclear cell; focal, minimal, pelvis
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2009	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Cortex Available For Evaluation.
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
NERVE, SCIATIC : Infiltration, mononuclear cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : (Comment) no DRGs on lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2010	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
NERVE, SCIATIC : Infiltration, mononuclear cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2011	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2012	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2013	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2014	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2015	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) red, muscle. (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2016	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2017	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2018	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2019	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2020	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2501	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, SALIVARY, MANDIBULAR : Infiltration, mononuclear cell; interstitial, focal, minimal
GLAND, THYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; perivascular, focal, minimal, pelvis
NERVE, OPTIC : (Note) One Of A Pair Available For Evaluation.
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2502	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

BONE MARROW, STERNUM : Hematopoietic cells, increased; diffuse, minimal
GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal, follicle
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) lumbar section
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2503	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

EYE : (Comment) second eye too damaged for evaluation
EYE : (Note) One Of A Pair Available For Evaluation.
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
LUNG : Aggregate; focal, minimal, macrophage
LYMPH NODE, MANDIBULAR : (Comment) tissue sampled is adipose tissue
SITE, ADMINISTRATION, 1 : Hemorrhage; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Cyst; squamous, focal, minimal : (Comment) lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, MANDIBULAR - Not Present In Wet Tissues.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2504	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) Subcutis, Red (TGL) [SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

BONE MARROW, STERNUM : Hematopoietic cells, increased; diffuse, minimal
GLAND, ADRENAL : (Note) Only Cortex And One Medulla Available For Evaluation.
GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
NERVE, SCIATIC : Infiltration, mononuclear cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Hemorrhage; focal, minimal, subcutaneous tissue [SITE, ADMINISTRATION, 2 : Discoloration, dark : (Comment) Subcutis, Red (G)]
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2505	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, THYROID : Ectopia; thymic
KIDNEY : Infiltration, mononuclear cell; perivascular, focal, minimal, pelvis
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GALLBLADDER - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2506	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

LYMPH NODE, INGUINAL : (Comment) second sample is mammary gland
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.
LYMPH NODE, INGUINAL : Cellularity, increased; lymphoid, minimal
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2507	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Basophilia; tubular, focal, minimal
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic section
URETER : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2508	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SPINAL CORD : Vacuolation; neuronal, focal, minimal, ganglion; dorsal root : (Comment) thoracic and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2509	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Basophilia; tubular, focal, minimal
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 1 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Edema; focal, minimal, subcutaneous tissue
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2510	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

LYMPH NODE, LUMBAR : Enlargement : (Comment) bilateral, up to 5x2x2mm (TGL) [NO CORRELATE : No correlating lesion (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
NERVE, SCIATIC : Infiltration, mixed cell; perineurial, focal, minimal
SITE, ADMINISTRATION, 1 : Inflammation, mononuclear cell; focal, minimal, subcutaneous tissue; myofiber
SITE, ADMINISTRATION, 2 : Inflammation, mixed cell; focal, minimal, subcutaneous tissue; myofiber
NO CORRELATE : No correlating lesion [LYMPH NODE, LUMBAR : Enlargement : (Comment) bilateral, up to 5x2x2mm (G)]

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, LUMBAR; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; OVARY; OVIDUCT; PANCREAS; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GALT - Not Present In Section.
GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2511	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2512	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2513	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2514	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2515	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2516	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2517	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2518	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2519	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2520	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Terminal Euthanasia		
		Study Day (Week) of Death:	45 (7)		

Gross Pathology Observations [Correlation]:

LIVER : Prominent lobular architecture : (Comment) All lobes (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1618	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Found Dead		
		Study Day (Week) of Death:	39 (6)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GALT : (Note) Postmortem Change Present.
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Comment) Sample is ganglion
KIDNEY : (Note) Postmortem Change Present.
LUNG : Congestion; agonal, diffuse, mild
LYMPH NODE, INGUINAL : (Note) Postmortem Change Present.
OVARY : (Note) Postmortem Change Present.
OVIDUCT : (Note) Postmortem Change Present.
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) Cervical, thoracic and lumbar sections
VAGINA : (Note) Postmortem Change Present.
UTERUS/CERVIX : (Note) Postmortem Change Present.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SPLEEN; THYMUS; TONGUE; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

EYE - Postmortem Change Precludes Evaluation.
GALLBLADDER - Postmortem Change Precludes Evaluation.
GLAND, PITUITARY - Not Present In Section.
GLAND, THYROID - Postmortem Change Precludes Evaluation.
LARGE INTESTINE, CECUM - Postmortem Change Precludes Evaluation.
LARGE INTESTINE, COLON - Postmortem Change Precludes Evaluation.
LARGE INTESTINE, RECTUM - Postmortem Change Precludes Evaluation.
SMALL INTESTINE, DUODENUM - Postmortem Change Precludes Evaluation.
SMALL INTESTINE, ILEUM - Postmortem Change Precludes Evaluation.
SMALL INTESTINE, JEJUNUM - Postmortem Change Precludes Evaluation.
STOMACH - Postmortem Change Precludes Evaluation.
TRACHEA - Postmortem Change Precludes Evaluation.
URETER - Postmortem Change Precludes Evaluation.
URINARY BLADDER - Postmortem Change Precludes Evaluation.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1101	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

THYMUS : Small (TGL) [THYMUS : Atrophy; mild (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LIVER : Infiltration, mononuclear cell; focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) lumbar section
THYMUS : Atrophy; mild [THYMUS : Small (G)]

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1102	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
LYMPH NODE, INGUINAL : (Comment) second sample is adipose tissue
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1103	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
LYMPH NODE, INGUINAL : (Comment) second sample is adipose tissue
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) Cervical and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1104	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, THYROID : Cyst; focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LYMPH NODE, INGUINAL : (Comment) samples are adipose tissue

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, INGUINAL - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1105	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1106	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
KIDNEY : Basophilia; tubular, focal, minimal
LYMPH NODE, INGUINAL : (Comment) second sample is adipose tissue
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1107	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) cervical section
TESTIS : Hypospermatogenesis; bilateral, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1108	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
KIDNEY : Cyst; tubular, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1109	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Comment) second sample is Harderian gland
GLAND, ADRENAL : (Note) One Of A Pair Available For Evaluation.
GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, SALIVARY, MANDIBULAR : Infiltration, mononuclear cell; focal, minimal
LYMPH NODE, INGUINAL : (Comment) sections are adipose and muscle

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, INGUINAL - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1110	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Cortex And One Medulla Available For Evaluation.
GLAND, SALIVARY, MANDIBULAR : (Comment) second sample is lymph node
GLAND, SALIVARY, MANDIBULAR : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LYMPH NODE, MANDIBULAR : (Comment) sample is adipose tissue and salivary gland
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.
LYMPH NODE, MANDIBULAR - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1111	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1112	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1113	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1114	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1115	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1116	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1117	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1118	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1119	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1120	Group:	1	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

TRACHEA : Fluid accumulation, pale : (Comment) frothy

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1601	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

LUNG : Focus, dark : (Comment) right cranial lobe, up to 2mm diameter, few, red. (TGL) [LUNG : Congestion; agonal, diffuse, minimal (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Gross Pathology - The following Tissues were Not Examined:

OVARY - Lost During Necropsy.

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
LIVER : Necrosis; focal, minimal
LIVER : Infiltration, mononuclear cell; focal, minimal
LUNG : Congestion; agonal, diffuse, minimal [LUNG : Focus, dark : (Comment) right cranial lobe, up to 2mm diameter, few, red. (G)]
LUNG : Aggregate; focal, minimal, macrophage
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic & lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.
OVARY - Lost During Necropsy.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1602	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Distalis Available For Evaluation.
GLAND, THYROID : Ectopia; thymic
KIDNEY : Basophilia; tubular, focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section; no DRGs in lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1603	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
LIVER : Infiltration, mononuclear cell; focal, minimal
LYMPH NODE, INGUINAL : (Comment) second sample is muscle
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.
URETER : (Comment) samples are adipose tissue

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

URETER - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1604	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
SPINAL CORD : (Comment) no DRGs in lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1605	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1606	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, HARDERIAN : Infiltration, mononuclear cell; focal, minimal
GLAND, SALIVARY, MANDIBULAR : Infiltration, mononuclear cell; focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1607	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, HARDERIAN : Infiltration, mononuclear cell; focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1608	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, THYROID : Ectopia; thymic
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
LIVER : Infiltration, mononuclear cell; focal, minimal
SPINAL CORD : (Comment) No DRGs in thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1609	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, SALIVARY, PAROTID : (Comment) samples are both mammary gland
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) Cervical and thoracic sections; no DRGs in lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

GLAND, SALIVARY, PAROTID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1610	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : (Note) Only Cortex And One Medulla Available For Evaluation.
GLAND, SALIVARY, MANDIBULAR : Infiltration, mononuclear cell; focal, minimal
GLAND, THYROID : Cyst; focal, minimal
GLAND, THYROID : Ectopia; thymic
SPINAL CORD : (Comment) No DRGs in thoracic section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1611	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1612	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1613	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1614	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1615	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1616	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1617	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1619	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	1620	Group:	1	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2101	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2102	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, THYROID : Cyst; focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2103	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2104	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

BRAIN : (Comment) Only one olfactory lobe
GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2105	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

LUNG : Discoloration, mottled : (Comment) all lobes (TGL) [LUNG : Congestion; agonal, diffuse, minimal (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

LUNG : Congestion; agonal, diffuse, minimal [LUNG : Discoloration, mottled : (Comment) all lobes (G)]

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2106	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

LUNG : Discoloration, mottled : (Comment) all lobes (TGL) [LUNG : Congestion; agonal, multifocal, minimal (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal
LUNG : Congestion; agonal, multifocal, minimal [LUNG : Discoloration, mottled : (Comment) all lobes (G)]
SPINAL CORD : (Comment) No DRGs in thoracic section; lumbar section damaged

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2107	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
KIDNEY : Cyst; tubular, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2108	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal
SPINAL CORD : (Comment) No DRGs in thoracic section
TESTIS : Hypospermatogenesis; unilateral, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2109	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
LYMPH NODE, MANDIBULAR : (Comment) Tissue sampled is adipose and lacrimal gland
SPINAL CORD : (Comment) No DRGs in lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, MANDIBULAR - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2110	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Histopathology - The following Tissues were Not Examined:

GLAND, PARATHYROID - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2111	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2112	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2113	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2114	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2115	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2116	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2117	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2118	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2119	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2120	Group:	2	Sex:	Male
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; EPIDIDYMIS; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, PROSTATE; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, SEMINAL VESICLE; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; TESTIS; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2601	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
SPINAL CORD : (Comment) No DRGs in cervical and thoracic sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2602	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

OVARY : Cyst, dark : (Comment) red, bilateral, two, up to 7x6mm, burst at necropsy (TGL) [NO CORRELATE : No correlating lesion (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal
KIDNEY : Infiltration, mononuclear cell; interstitial, focal, minimal
KIDNEY : Basophilia; tubular, focal, minimal
OVARY : (Comment) Cyst not present in section
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) no DRGs in thoracic section
NO CORRELATE : No correlating lesion [OVARY : Cyst, dark : (Comment) red, bilateral, two, up to 7x6mm, burst at necropsy (G)]

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2603	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, HARDERIAN : Dilatation; focal, minimal
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Comment) neurohypophysis not present
GLAND, THYROID : Ectopia; thymic
KIDNEY : Basophilia; tubular, focal, minimal
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

URETER - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2604	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

OVARY : Focus, dark : (Comment) Right, few, black, pinpoint (TGL) [OVARY : Congestion; multifocal, minimal (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
GLAND, THYROID : Ectopia; thymic
OVARY : Cyst; epithelial, focal, minimal
OVARY : Congestion; multifocal, minimal [OVARY : Focus, dark : (Comment) Right, few, black, pinpoint (G)]
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) No DRGs in cervical section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2605	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, ADRENAL : Hyperplasia; focal, minimal, subcapsular cell
GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
LIVER : Infiltration, mononuclear cell; focal, minimal
LYMPH NODE, INGUINAL : (Comment) second sample is mammary gland
LYMPH NODE, INGUINAL : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2606	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, SALIVARY, PAROTID : (Comment) second sample is mammary gland, adipose and muscle
GLAND, SALIVARY, PAROTID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Cyst; focal, minimal
GLAND, THYROID : Ectopia; thymic
LYMPH NODE, INGUINAL : (Comment) Both samples are mammary gland
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) cervical, thoracic and lumbar sections

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, INGUINAL - Not Present In Section.

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2607	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, THYROID : Ectopia; thymic
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section; no DRGs in lumbar section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2608	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section; no DRGs in the cervical section

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2609	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2610	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

LIVER : Prominent lobular architecture : (Comment) all lobes (TGL) [NO CORRELATE : No correlating lesion (H)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology Observations [Correlation]:

GLAND, PARATHYROID : (Note) One Of A Pair Available For Evaluation.
GLAND, PITUITARY : (Note) Only Distalis Available For Evaluation.
SPINAL CORD : Vacuolation; neuronal, focal, minimal, dorsal root; ganglion : (Comment) thoracic section
NO CORRELATE : No correlating lesion [LIVER : Prominent lobular architecture : (Comment) all lobes (G)]

Histopathology - The following Tissues were Within Normal Limits:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; OVARY; OVIDUCT; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2611	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2612	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2613	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2614	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2615	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2616	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2617	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2618	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2619	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 17

Individual macroscopic and microscopic pathology

513351

Animal:	2620	Group:	2	Sex:	Female
Species:	Mouse	Strain:	CD-1		
		Dose:	70 ul		
		Removal Reason:	Recovery Euthanasia		
		Study Day (Week) of Death:	74 (11)		

Gross Pathology Observations [Correlation]:

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Protocol Required Tissues were Not Processed:

ARTERY, AORTA; BONE MARROW, STERNUM; BONE, FEMUR; BONE, STERNUM; BRAIN; ESOPHAGUS; EYE; GALLBLADDER; GALT; GLAND, ADRENAL; GLAND, HARDERIAN; GLAND, MAMMARY; GLAND, PARATHYROID; GLAND, PITUITARY; GLAND, SALIVARY, MANDIBULAR; GLAND, SALIVARY, PAROTID; GLAND, THYROID; HEART; KIDNEY; LARGE INTESTINE, CECUM; LARGE INTESTINE, COLON; LARGE INTESTINE, RECTUM; LIVER; LUNG; LYMPH NODE, INGUINAL; LYMPH NODE, MANDIBULAR; LYMPH NODE, MESENTERIC; MUSCLE, SKELETAL; NERVE, OPTIC; NERVE, SCIATIC; PANCREAS; SITE, ADMINISTRATION, 1; SITE, ADMINISTRATION, 2; SKIN; SMALL INTESTINE, DUODENUM; SMALL INTESTINE, ILEUM; SMALL INTESTINE, JEJUNUM; SPINAL CORD; SPLEEN; STOMACH; THYMUS; TONGUE; TRACHEA; URETER; URINARY BLADDER; OVARY; OVIDUCT; VAGINA; UTERUS/CERVIX

Appendix 18

AZD1222
513351 (1156PM)

Charles River Laboratories

Pathology Report	
Project name	AZD1222
Study number	513351
AstraZeneca reference no	1156PM
GLP compliance	Yes
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AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

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Appendix 18

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1. INTRODUCTION

This report presents the pathology findings in mice assigned to the study entitled AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery 513351 (1156PM).

2. MATERIALS AND METHODS

All animals were submitted for necropsy on Day 45 (Terminal Euthanasia) or Day 74 (Recovery Euthanasia), except for animal F1618 which was found dead before the scheduled euthanasia date.

Tissues required for microscopic evaluation were trimmed, processed routinely, embedded in paraffin, and stained with hematoxylin and eosin (H&E).

Microscopic evaluation was conducted by the undersigned board-certified veterinary pathologist on all protocol-specified tissues from the first 10 animals/sex in Groups 1 and 2 (main study phases) and early death animals. Tissues were evaluated by light microscopy, and the results were entered directly into a validated pathology computer program (Provantis® 10, Instem) for preparation of data tables.

A small number of protocol-required tissues were not present on the slides, or were of insufficient quality to permit evaluation, even after reasonable attempts were made to obtain further sections. The reasons why they were not evaluated have been recorded in the individual animal data.

2.1 Computerized systems

Critical computerized systems used in this study phase are listed in Table 1.

Table 1 Computerized systems

System Name	Version No.	Description of Data Collected and/or Analysed
Provantis®	10	Gross/Organ weights/Histopathology

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3. RESULTS

3.1 Mortality/unscheduled euthanasia

There was one unscheduled death during the course of this study (control Animal F1618). Many tissues showed post-mortem change but there were no microscopic findings that would account for the death of this animal.

3.2 Gross pathology

3.2.1 Scheduled euthanasia main study animals

No AZD1222-related gross findings were noted.

Gross findings (dark discoloration) seen at administration site 2 were considered incidental to the injection procedure and/or were of similar incidence in control and animals administered AZD1222 and, therefore, were considered to be procedural and unrelated to administration of AZD1222.

The gross finding observed in the liver of one female administered AZD1222 was of the nature commonly observed in this strain and age of mouse and, therefore, was considered unrelated to administration of AZD1222.

Gross findings are summarized in Table 2.

Table 2 Salient gross findings main study

Study phase	**Main**			
Viral Particle (VP)/dose	**0**	**3.7 x 10^{10}**	**0**	**3.7 x 10^{10}**
Sex	**Males**		**Females**	
Number of animals	**20**	**20**	**20**	**20**
Liver (No. examined)	(20)	(20)	(20)	(20)
Prominent lobular architecture	0	0	0	1
Site Admin, 2 (No. examined)	20	20	20	20
Discoloration, dark	1	2	0	1

3.2.2 Recovery animals

No AZD1222-related gross findings were noted.

All gross findings observed were of the nature commonly observed in this strain and age of mouse and, therefore, were considered unrelated to administration of AZD1222.

3.3 Organ weights

3.3.1 Main study animals

There was a test item-related higher spleen weight in both sexes, but with no correlating macroscopic or microscopic findings. Organ weight changes are summarized in Table 3.

Table 3 Salient organ weight data

Study phase	**Main**			
Sex	**Males**		**Females**	
Viral Particle (VP)/dose	**0**	**3.7 x 10^{10}**	**0**	**3.7 x 10^{10}**
Number of animals	**20**	**20**	**20**	**20**
Mean Terminal Body Weight (No. weighed)	20	20	20	20
Group mean value (g)	37.40	39.01*	29.70	30.44
Spleen (No. weighed)	(20)	(20)	(20)	(20)
Absolute value (g)	0.0910	0.1215***	0.1227	0.1738***
Relative to body weight (%)	0.24370	0.31106***	0.41039	0.56592***

Significantly different from control group 1 value Anova & Dunnett: * = $p \leq 0.05$, *** = $p \leq 0.001$.

Other differences in organs weights were considered unrelated to administration of AZD1222.

3.3.2 Recovery animals

The test item related higher weight seen in the spleens of main study animals was not present in recovery animals.

Other differences in organs weights were considered unrelated to administration of AZD1222.

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3.4 Histopathology

3.4.1 Main study animals

Minimal subcutaneous oedema was observed in the administration sites in male and female animals from both the control groups and those administered AZD1222 and was considered to be related to the route of administration.

Minimal mononuclear or mixed cell inflammation was observed in the subcutaneous tissue and underlying skeletal muscle at the administration sites in both male and female animals. This finding was of a higher incidence in animals administered AZD1222.

In some animals there was an extension of the inflammatory cells into the fascia and connective tissue below the skeletal muscle at the administration sites. This resulted in inflammatory cells being noted surrounding the epineurium/perineurium of the sciatic nerve samples. This finding was recorded as 'Inflammation perineurium' in the histopathology data. While sciatic epineurial/perineurial inflammatory cells were present in a small number of controls, the incidence was higher in animals administered AZD1222, and reflected the higher incidence of inflammatory cells noted at the administration sites of animals dosed AZD1222. The epineurial/perineurial inflammatory cells did not extend into the endoneurium, and no findings were present in the underlying axons, which appeared histologically normal. Inflammatory cells were not observed in the nerve roots contained within the lumbar spinal cord sections, confirming that the epineurial/perineurial inflammatory cells noted in the sciatic nerve samples resulted from an extension of the inflammation from the adjacent injection site. In the hind limb, inflammation around the sciatic nerve due to local extension from the administration site is a well-recognized effect (Sellers 2020).

Histopathology findings are summarized in Table 4.

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Table 4 Salient microscopic findings in the administration sites of main study animals

Study phase	Main			
Viral Particle (VP)/dose	**0**	**3.7 x 10^{10}**	**0**	**3.7 x 10^{10}**
Number of animals	**10**	**10**	**10**	**10**
Sex	**Males**		**Females**	
Administration site 1 (No. examined)	(10)	(10)	(10)	(10)
Inflammation, subcutaneous tissue; myofiber, minimal	2	10	1	10
Mononuclear cell	2	6	0	3
Mixed cell	0	4	1	7
Oedema, subcutaneous, minimal	8	9	7	5
Haemorrhage, subcutaneous, minimal	0	0	0	1
Administration site 2 (No. examined)	(10)	(10)	(10)	(10)
Inflammation, subcutaneous tissue; myofiber, minimal	4	10	1	9
Mononuclear cell	4	6	0	1
Mixed cell	0	4	1	8
Oedema, subcutaneous, minimal	9	9	10	4
Haemorrhage, subcutaneous, minimal	2	2	0	2
Congestion, subcutaneous, minimal	1	0	0	0
Sciatic Nerve (No. examined)	(10)	(10)	(10)	(10)
Inflammation, perineurial, minimal	0	9	2	9
Mononuclear cell	0	5	0	1
Mixed cell	0	4	2	8

The inflammation observed at the administration sites was of the nature commonly observed following intra-muscular injection of a vaccine (Greaves 2013) in this strain and age of mouse, and was considered non-adverse.

The small number of protocol-required tissues that could not be examined were spread throughout the treatment groups and therefore considered not to have impacted the quality or integrity of the study.

The remaining histopathology findings were considered unrelated to administration of AZD1222.

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3.4.2 Recovery animals

There were no histopathology findings considered related to the administration of AZD1222.

There were no findings in the administration sites or sciatic nerves in the Recovery animals, indicating complete recovery of the AZD1222 related inflammation.

4. DISCUSSION

Animals dosed with AZD1222 showed higher spleen weight in both sexes, but with no correlating macroscopic or microscopic findings. This spleen weight change was not present in the recovery animals. The higher incidence of inflammation at the administration sites in animals dosed with AZD1222 is consistent with that expected following the intramuscular administration of a vaccine and resulted in the extension of the inflammation into the adjacent sciatic nerve perineurium. There were no findings in the administration sites or sciatic nerve of the recovery animals showing complete recovery of the inflammation.

5. CONCLUSION

Administration of AZD1222 by intramuscular injection intermittently (on Days 1, 22 and 43) to mice was not associated with mortality or toxicity.

The minimal mixed and/or mononuclear cell inflammation in the subcutaneous tissues and skeletal muscle of the administration sites and adjacent sciatic nerve of animals dosed with AZD1222 were consistent with the anticipated findings after intra-muscular injection of vaccines, were no longer present in any of the recovery animals, and were not considered adverse.

6. REFERENCES

Greaves 2013
Greaves P, Chouinard L, Ernst H, Mecklenburg L, Pruimboom-Brees I, Rinke M *et al*. Proliferative and non-proliferative lesions of the rat and mouse soft tissue, skeletal muscle and mesothelium. *J Toxicol Pathol* 2013; **26** (3 Suppl): 1S–26S.

Sellers 2020
Sellers R, Nelson K, Bennet B, Wolf J, Tripathi N *et al*. Scientific and Regulatory Policy Committee Points to Consider: Approaches to the Conduct and Interpretation of Vaccine Safety Studies for Clinical and Anatomic Pathologists. *Toxicologic Pathology* 2020, **48**(2) 257-276.

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7. REPORT APPROVAL

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External pathology peer review certificate

ASTRAZENECA HISTOPATHOLOGY PEER REVIEW FORM

Study Title: AZD1222 (ChAdOx1-nCovd-19): A 6 Week Intermittent Dosing Intramuscular Vaccine Toxicity Study in the Mouse with a 4 Week Recovery

AZ Compound: AZD1222	CRO: CRL Edinburgh
AZ Sponsor Reference: 1156PM	CRO Study No: 513351
Reviewing Pathologist: s 22	Study Pathologist: s 22
Credentials: VetMB, DipACVP	Credentials: FRCPath
Affiliation: AZ CPSS	Affiliation: CRL Edinburgh

Inclusive dates of Digital Slide Review and details of the animals and tissues examined
Main test phase:
Monday 30th November – Wednesday 2nd December 2020

2001, 2002, 2003, 2501, 2502, 2503 – full tissue list

All group 2 animals – Brain, spinal cord, sciatic nerve, administration sites (1 and 2).

Recovery phase:
Wednesday 23rd December-Thursday 24th December 2020

1618, 2101, 2102, 2610, 2608 – full tissue list

All group 2 animals – Brain, spinal cord, sciatic nerve, administration sites (1 and 2).

Outcome of Peer Review:
The final pathology report and tabular data represent a consensus opinion between the study pathologist and AstraZeneca review pathologist

The AstraZeneca Pathologist confirms that the relevant sections of the AstraZeneca guidance document covering peer review have been followed. The exact number of animals and tissues examined was left to the discretion of the peer review pathologist.

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Date: 26.12.2020