



Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of Responsible Analyst

A sample of therapeutic goods, bearing TGA sample number 2107002694 has been examined and analysed

Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

ARTG Number: 346290
Name: COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine 30 micrograms/0.3 mL concentrated suspension for injection vial
Sponsor: Pfizer Australia Pty Ltd
Batch Number: FE3430
Expiry Date: 31-October-2021
Dosage Form: Injection, concentrated

TEST	RESULT	REQUIREMENT
COVID Lot Release Parameters	14/07/2021	

This Certificate has been signed and issued electronically by the Responsible Analyst nominated under subregulation 25(3)(c) of the *Therapeutic Goods Regulations 1990*

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TEST	RESULT	REQUIREMENT
BNT162b2 Sample Tests		
- BNT162b2 RNA Encapsulation by Fluorescence	95 %	
- BNT162b2 RNA content by Fluorescence	0.48 mg/mL	
- BNT162b2 ALC-0315 content by HPLC-CAD	6.67 mg/mL	
- BNT162b2 ALC-0159 content by HPLC-CAD	0.80 mg/mL	
- BNT162b2 DSPC content by HPLC-CAD	1.50 mg/mL	
- BNT162b2 Cholesterol content by HPLC-CAD	2.99 mg/mL	
- BNT162b2 Lipid identities (x4) by HPLC-CAD	PASS	
- BNT162b2 Identity of encoded RNA sequence by RT-PCR	confirmed	
- BNT162b2 RNA integrity by Capillary Gel Electrophoresis	68 %	
- BNT162b2 RNA integrity by Capillary Gel Electrophoresis - system suitability	Pass	
- BNT162b2 RNA integrity by Capillary Gel Electrophoresis - Late Migrating Species (LMS)	3 %	
- BNT162b2 Endotoxin by Chromogenic	<5.0 EU/mL	
BNT162b2 Sample Tests		
- BNT162b2 LNP Size by DLS		
- BNT162b2 LNP Polydispersity by DLS		

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