Australian Government
Department of Health
Therapeutic Goods Administration
Laboratories Branch

Owner: <QPulse_DocOwner>	**Number:** <QPulse_DocNumber>
Author: <QPulse_DocAuthor>	**Version:** <QPulse_DocRevisionNumber>
Active: <QPulse_DocActiveDate>	**Review:** <QPulse_DocReviewDate>
Title: <QPulse_DocTitle>	

Worksheet for Zetasizer – DLS – Particle Size and polydispersity

Test Details			
SOP QPulse #	Bio-BPC-Method-27	**Analysist**	[redacted]
TRIM link to data files	D21-3231364	**Test Date**	19/10/2021

Pipettes & Equipment	
Name	**LIMS#**
P20	32677
P200	5649
P1000	5643
Enter text.	Enter text.
Enter text.	Enter text.
Enter text.	Enter text.

Reagents & Consumables			
Details	**Catalog #**	**Lot/Batch Number**	**Expiry date**
Nanosphere size standard 20 nm	Enter text.	Enter text.	Enter a date.
Nanosphere size standard 50 nm	Enter text.	Enter text.	Enter a date.
Nanosphere size standard 150 nm	3150A	236572	31/02/2024
Nanosphere size standard 200 nm	Enter text.	Enter text.	Enter a date.
PBS	In house	20210624/01	24/06/2022
Cuvettes	DTS0012	1005/1007004	Enter a date.
Enter text.	Enter text.	Enter text.	Enter a date.
Enter text.	Enter text.	Enter text.	Enter a date.
Enter text.	Enter text.	Enter text.	Enter a date.

Zetasizer Performance Test				
Size Standard	**Parameter**	**Limits**	**Results**	**Comments**
150 nm	Average of Mean hydrodynamic diameter (nm)	+/-10nm of CoA (142-162 nm)	158.4	PASS
150 nm	%RSD of mean hydrodynamic diameter	≤ 10%	1.163	PASS
System Suitability Criteria				
Product tested	**Parameter**	**Limits**	**Results**	**Comments**
150 nm standard	Mean hydrodynamic diameter (nm)	+/-10nm of CoA (142-162 nm)	158.4	PASS
150 nm standard	Mean hydrodynamic diameter (RSD)	≤ 5%	1.163	PASS
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.
Enter text.	Enter text.	Enter text.	Enter text.	Enter text.

Assay Acceptance Criteria				
Product tested	**Parameter**	**Limits**	**Results**	**Comments**
150 nm standard (beginning and end of assay)	Mean hydrodynamic diameter (nm)	+/-10nm of CoA (142-162 nm)	159	PASS
150 nm standard (beginning and end of assay)	Mean hydrodynamic diameter (RSD)	≤ 10%	1.297	PASS
Reference Material 2108002914 - EE8493	Mean hydrodynamic diameter (RSD)	≤ 5%	1.108	PASS
Reference Material 2108002914 - EE8493	Mean hydrodynamic diameter (nm)	≤ 200 nm	79.4	PASS
Reference Material 2108002914 - EE8493	PDI	≤ 0.3	0.1621	PASS
Drug Product tested - 2110003744	Mean hydrodynamic diameter RSD	[redacted]	0.8364	PASS
Drug Product tested	Mean hydrodynamic diameter RSD	[redacted]	Enter text.	Choose an item.
Drug Product tested	Mean hydrodynamic diameter RSD	[redacted]	Enter text.	Choose an item.
Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.

System suitability standard & reference material dilutions / calculation / notes
SYSTEM SUITABILITY STANDARD - 5 uL of 150 nm standard added to 4995 ul of 0.1 um filtered PBS REFERENCE MATERIAL: - 0.2 mg/mL RM --> 80 µL x 0.53 mg/mL + 132 µL PBS - 0.002 mg/mL RM --> 10 µL x 0.2 mg/mL + 990 µL PBS

Sample 1 Details	
LIMS #	**2110003744**
BATCH #	FL3560
EXPIRY	28/02/2022

Test Results

Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)	[redacted]				PASS
Polydispersity Index					PASS
Result quality	N/A	Enter text.			Choose an item.

Sample Dilutions / Calculation / Notes

0.2 mg/mL DP --> 80 µL x 0.5 mg/mL + 120 µL PBS
0.002 mg/mL DP --> 10 µL x 0.2 mg/mL + 990 µL PBS

Sample Results	
PASS	
Analysist	[redacted]
Checked by	[redacted]

Sample 2 Details	
LIMS #	Click or tap here to enter text.
BATCH #	Click or tap here to enter text.
EXPIRY	00/0/2022

Test Results

Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)	[redacted]	Enter text.	Enter text.	Enter text.	PASS
Polydispersity Index		Enter text.	Enter text.	Enter text.	PASS
Result quality	N/A	Enter text.			Choose an item.

Sample Dilutions / Calculation / Notes

0.2 mg/mL DP --> 80 µL x 0.5 mg/mL + 120 µL PBS
0.002 mg/mL DP --> 10 µL x 0.2 mg/mL + 990 µL PBS

Sample Results	
Choose an item.	
Analysist	[redacted]
Checked by	[redacted]

Sample 3 Details	
LIMS #	Click or tap here to enter text.
BATCH #	Click or tap here to enter text.
EXPIRY	Enter date.

Test Results

Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)	[redacted]	Enter text.	Enter text.	Enter text.	Choose an item.
Polydispersity Index		Enter text.	Enter text.	Enter text.	Choose an item.
Result quality	Enter text.	Enter text.			Choose an item.

Sample Dilutions / Calculation / Notes

Enter text.

Sample Results

Choose an item.

Analysist	[redacted]
Checked by	[redacted]

Sample 4 Details	
LIMS #	Click or tap here to enter text.
BATCH #	Click or tap here to enter text.
EXPIRY	Enter date.

Test Results

Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)	Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.
Polydispersity Index	Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.
Result quality	Enter text.	Enter text.			Choose an item.

Sample Dilutions / Calculation / Notes

Enter text.

Sample Results

Choose an item.

Analysist	Enter text.
Checked by	Enter text.

Sample 5 Details	
LIMS #	Click or tap here to enter text.
BATCH #	Click or tap here to enter text.
EXPIRY	Enter date.

Test Results

Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)	Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.
Polydispersity Index	Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.
Result quality	Enter text.	Enter text.			Choose an item.

Sample Dilutions / Calculation / Notes

Enter text.

Sample Results

Choose an item.

Analysist	Enter text.
Checked by	Enter text.

Sample 6 Details	
LIMS #	Click or tap here to enter text.
BATCH #	Click or tap here to enter text.
EXPIRY	Enter date.

Test Results

Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)	Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.
Polydispersity Index	Enter text.	Enter text.	Enter text.	Enter text.	Choose an item.
Result quality	Enter text.	Enter text.			Choose an item.

Sample Dilutions / Calculation / Notes

Enter text.

Sample Results

Choose an item.

Analysist	Enter text.
Checked by	Enter text.

Notes
Enter text