



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

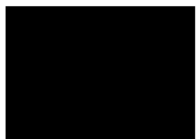
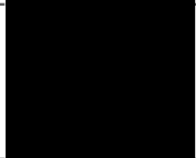

### Worksheet for Zetasizer – DLS – Particle Size and polydispersity

Test Details			
<b>SOP QPulse #</b>	Bio-BPC-Method-27	<b>Analysist</b>	██████
<b>TRIM link to data files</b>	D21-3231364	<b>Test Date</b>	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.

<b>Zetasizer Performance Test</b>				
<b>Size Standard</b>	<b>Parameter</b>	<b>Limits</b>	<b>Results</b>	<b>Comments</b>
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
<b>System Suitability Criteria</b>				
<b>Product tested</b>	<b>Parameter</b>	<b>Limits</b>	<b>Results</b>	<b>Comments</b>
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.
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
<b>Drug Product tested - 2110003744</b>	Mean hydrodynamic diameter RSD		0.8364	PASS
<b>Drug Product tested</b>	Mean hydrodynamic diameter RSD		Enter text.	Choose an item.
<b>Drug Product tested</b>	Mean hydrodynamic diameter RSD		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  $\mu\text{L}$  of 150 nm standard added to 4995  $\mu\text{L}$  of 0.1  $\mu\text{m}$  filtered PBS

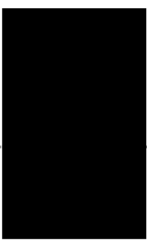



REFERENCE MATERIAL:

- 0.2 mg/mL RM --> 80  $\mu\text{L}$  x 0.53 mg/mL + 132  $\mu\text{L}$  PBS

- 0.002 mg/mL RM --> 10  $\mu\text{L}$  x 0.2 mg/mL + 990  $\mu\text{L}$  PBS

Sample 1 Details					
<b>LIMS #</b>	2110003744				
<b>BATCH #</b>	FL3560				
<b>EXPIRY</b>	28/02/2022				
Test Results					
Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)				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					
<b>Analysist</b>	██████				
<b>Checked by</b>	██████				

Sample 2 Details					
<b>LIMS #</b>	Click or tap here to enter text.				
<b>BATCH #</b>	Click or tap here to enter text.				
<b>EXPIRY</b>	00/0/2022				
Test Results					
Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)		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.					
<b>Analysist</b>					
<b>Checked by</b>					

Sample 3 Details					
<b>LIMS #</b>	Click or tap here to enter text.				
<b>BATCH #</b>	Click or tap here to enter text.				
<b>EXPIRY</b>	Enter date.				
Test Results					
Parameters	Limits	Results			Comments
		Average	SD	%RSD	
Mean hydrodynamic diameter (nm)		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.					
<b>Analysist</b>					
<b>Checked by</b>					

Sample 4 Details					
<b>LIMS #</b>	Click or tap here to enter text.				
<b>BATCH #</b>	Click or tap here to enter text.				
<b>EXPIRY</b>	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.					
<b>Analysist</b>	Enter text.				
<b>Checked by</b>	Enter text.				



Sample 5 Details					
<b>LIMS #</b>	Click or tap here to enter text.				
<b>BATCH #</b>	Click or tap here to enter text.				
<b>EXPIRY</b>	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.					
<b>Analysist</b>	Enter text.				
<b>Checked by</b>	Enter text.				

Sample 6 Details					
<b>LIMS #</b>	Click or tap here to enter text.				
<b>BATCH #</b>	Click or tap here to enter text.				
<b>EXPIRY</b>	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.					
<b>Analysist</b>		Enter text.			
<b>Checked by</b>		Enter text.			

**Notes**

Enter text