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Worksheet for Zetasizer – DLS – Particle Size and polydispersity

Test Details			
SOP QPulse #	Bio-BPC-Method-27	Analysist	██████
TRIM link to data files	D21-3255011	Test Date	25/10/2021

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)	159.8	PASS
150 nm	%RSD of mean hydrodynamic diameter	≤ 10%	1.045	PASS
System Suitability Criteria				
Product tested	Parameter	Limits	Results	Comments
150 nm standard	Mean hydrodynamic diameter (nm)	+/-10nm of CoA (142-162 nm)	159.8	PASS
150 nm standard	Mean hydrodynamic diameter (RSD)	≤ 5%	1.045	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)	159.1	PASS
150 nm standard (beginning and end of assay)	Mean hydrodynamic diameter (RSD)	≤ 10%	0.8813	PASS
Reference Material 2108002914 - EE8493	Mean hydrodynamic diameter (RSD)	≤ 5%	0.498	PASS
Reference Material 2108002914 - EE8493	Mean hydrodynamic diameter (nm)	≤ 200 nm	79	PASS
Reference Material 2108002914 - EE8493	PDI	≤ 0.3	0.1263	PASS
Drug Product tested - 2110003737	Mean hydrodynamic diameter RSD		1.145	PASS
Drug Product tested	Mean hydrodynamic diameter RSD		Enter text.	Choose an item.
Drug Product tested	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 μL of 150 nm standard added to 4995 μL of 0.1 μm 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 #	2110003737				
BATCH #	FH3221				
EXPIRY	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					
Analysist	██████████				
Checked by	██████████				

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)		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					
Checked by					

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