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|---------------------------------------|--|
| <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> | D21-3279840       | <b>Test Date</b> | 1/11/2021 |

| 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%                       | 0.4336         | 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%                        | 0.4336         | 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<br>(beginning and<br>end of assay) | Mean<br>hydrodynamic<br>diameter (nm)  | +/-10nm of CoA<br>(142-162 nm) | 158.2       | PASS            |
| 150 nm standard<br>(beginning and<br>end of assay) | Mean<br>hydrodynamic<br>diameter (RSD) | ≤ 10%                          | 0.648       | PASS            |
| Reference<br>Material<br>2108002914 -<br>EE8493    | Mean<br>hydrodynamic<br>diameter (RSD) | ≤ 5%                           | 0.6462      | PASS            |
| Reference<br>Material<br>2108002914 -<br>EE8493    | Mean<br>hydrodynamic<br>diameter (nm)  | ≤ 200 nm                       | 79.34       | PASS            |
| Reference<br>Material<br>2108002914 -<br>EE8493    | PDI                                    | ≤ 0.3                          | 0.1526      | PASS            |
| <b>Drug Product<br/>tested -<br/>2110003905</b>    | Mean<br>hydrodynamic<br>diameter RSD   | ■                              | 1.165       | PASS            |
| <b>Drug Product<br/>tested</b>                     | Mean<br>hydrodynamic<br>diameter RSD   | ■                              | Enter text. | Choose an item. |
| <b>Drug Product<br/>tested</b>                     | Mean<br>hydrodynamic<br>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>  | 2110003905 |             |    |      |                 |
| <b>BATCH #</b>   | FL7649     |             |    |      |                 |
| <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<br>0.002 mg/mL DP --> 10 µL x 0.2 mg/mL + 990 µL PBS |            |             |    |      |                 |
| Sample Results   |            |             |    |      |                 |
| PASS   |            |             |    |      |                 |
| <b>Analysist</b>   | [REDACTED] |             |    |      |                 |
| <b>Checked by</b>  | [REDACTED] |             |    |      |                 |

| 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<br>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