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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>            | Enter text. | <b>Analysist</b> | ████████   |
| <b>TRIM link to data files</b> | Enter text. | <b>Test Date</b> | 23/06/2021 |

| Pipettes & Equipment |             |
|----------------------|-------------|
| Name                 | LIMS#       |
| P20                  | 32891       |
| P200                 | 32892       |
| 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           | 29/02/2024    |
| Nanosphere size standard 200 nm | Enter text. | Enter text.      | Enter a date. |
| PBS                             | In house    | 20200929/02      | 29/09/2021    |
| 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) | 140-160 nm       | 148.1          | PASS            |
| 150 nm                             | %RSD of mean hydrodynamic diameter         | ≤ 10%?           | 3.801          | 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)            | Within +/- 10 nm | 148.1          | PASS            |
| 150 nm standard                    | Mean hydrodynamic diameter (RSD)           | ≤ 5%             | 0.3.801        | 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.     |

| <b>Assay Acceptance Criteria</b>                   |  |   |                |                 |
|--|--|---|----------------|-----------------|
| <b>Product tested</b>                              | <b>Parameter</b>                       | <b>Limits</b>   | <b>Results</b> | <b>Comments</b> |
| 150 nm standard<br>(beginning and<br>end of assay) | Mean<br>hydrodynamic<br>diameter (nm)  | Within +/- 10 nm  | 154.5          | PASS            |
| 150 nm standard<br>(beginning and<br>end of assay) | Mean<br>hydrodynamic<br>diameter (RSD) | ≤ 10%   | 5.208          | PASS            |
| Reference<br>Material - DP                         | Mean<br>hydrodynamic<br>diameter (RSD) | ≤ 5%  | 1.1            | PASS            |
| Reference<br>Material - DP                         | Mean<br>hydrodynamic<br>diameter (nm)  | ≤ 200 nm  | 74.86          | PASS            |
| Reference<br>Material - DP                         | PDI                                    | ≤ 0.3   | 0.1351         | PASS            |
| Drug Product<br>tested -<br>2107002694             | Mean<br>hydrodynamic<br>diameter RSD   |  | 0.4219         | PASS            |
| Enter text.  | Enter text.                            | Enter text.   | Enter text.    | Choose an item. |
| Enter text.  | Enter text.                            | Enter text.   | 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 4996  $\mu\text{L}$  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>  | 2107002694  |             |    |      |                 |
| <b>BATCH #</b>   | FE3430      |             |    |      |                 |
| <b>EXPIRY</b>  | 31/10/2021  |             |    |      |                 |
| 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>  | Enter text. |             |    |      |                 |

| 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>                          | 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 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. | 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 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.                      |             |             |             |                 |
|---|----------------------------------|-------------|-------------|-------------|-----------------|
| <b>Test Results</b>                           |                                  |             |             |             |                 |
| 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. |
| <b>Sample Dilutions / Calculation / Notes</b> |                                  |             |             |             |                 |
| Enter text.                                   |                                  |             |             |             |                 |
| <b>Sample Results</b>                         |                                  |             |             |             |                 |
| Choose an item.                               |                                  |             |             |             |                 |
| <b>Analysist</b>                              |                                  |             | Enter text. |             |                 |
| <b>Checked by</b>                             |                                  |             | Enter text. |             |                 |
| <b>Sample 6 Details</b>                       |                                  |             |             |             |                 |
| <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. |             |             |             |                 |
|---|-------------|-------------|-------------|-------------|-----------------|
| <b>Test Results</b>                           |             |             |             |             |                 |
| 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. |
| <b>Sample Dilutions / Calculation / Notes</b> |             |             |             |             |                 |
| Enter text.                                   |             |             |             |             |                 |
| <b>Sample Results</b>                         |             |             |             |             |                 |
| Choose an item.                               |             |             |             |             |                 |
| <b>Analysist</b>                              |             |             | Enter text. |             |                 |
| <b>Checked by</b>                             |             |             | Enter text. |             |                 |

|              |
|--------------|
| <b>Notes</b> |
| Enter text   |

