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### 3.2.P.5.4 BATCH ANALYSES

Batch analysis data are generated for mRNA-1273 Drug Product (DP) according to approved specifications. Specifications are described in [Section 3.2.P.5.1](#), analytical procedures are described in [Section 3.2.P.5.2](#) and validation of analytical procedures is described in [Section 3.2.P.5.3](#). Refer to [Section 3.2.P.2.3 {Comparability}](#) for specification changes and analytical procedure changes that have occurred throughout development.

Batch analyses are presented in this section for the following lot groupings:

- **Registration lots:** Commercial scale process performance qualification and comparability lots from Scale B manufacturing,
  - Lots of the 6.3-mL image are identified in [Table 1](#) with batch analysis data reported in [Table 2](#) through [Table 7](#).
  - Lots of the 8.0-mL image are identified in [Table 8](#) with batch analysis data reported in [Table 9](#) through [Table 14](#).

Catalent lot numbers and associated Moderna lot numbers for Catalent-manufactured lots are provided as the unlabeled drug product (UDP) lot numbers on the Certificates of Analysis, because release sampling occurred prior to labeling. Baxter lot numbers and associated Moderna lot numbers for Baxter manufactured lots are provided as the labeled drug product (LDP) lot numbers on the Certificates of Analysis, because release sampling occurred post-labeling. The Certificates of Analysis are provided as attachments (see [Table 22](#) for index).

- **Clinical lots:** Lots used for Phase 1, Phase 2, and pivotal Phase 3 clinical trials are identified in [Table 15](#). Batch analysis data are reported in [Table 16](#) through [Table 21](#). The Certificates of Analysis are provided as attachments (see [Table 22](#) for index).

**Table 1: Comparative Batch Analysis – mRNA-1273 Drug Product Registration Lots - 6.3 mL Image**

| Lot                                                                                       | Use                | Manufacturer | Filling Line          | DOM         | Specification         |
|-------------------------------------------------------------------------------------------|--------------------|--------------|-----------------------|-------------|-----------------------|
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     | Comparability, PPQ | Catalent     | Flexible Filling Line | 11 Oct 2020 | SPC-1128<br>Version 2 |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     | Comparability, PPQ | Catalent     | Flexible Filling Line | 25 Oct 2020 | SPC-1128<br>Version 4 |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) | Comparability, PPQ | Catalent     | Flexible Filling Line | 25 Oct 2020 | SPC-1128<br>Version 4 |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     | Comparability, PPQ | Catalent     | Flexible Filling Line | 09 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     | Comparability, PPQ | Catalent     | Flexible Filling Line | 03 Dec 2020 | SPC-1128<br>Version 4 |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) | Comparability, PPQ | Catalent     | Flexible Filling Line | 10 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     | Comparability, PPQ | Catalent     | Flexible Filling Line | 20 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) | Comparability, PPQ | Catalent     | Flexible Filling Line | 20 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A)     | Comparability, PPQ | Catalent     | Flexible Filling Line | 22 Nov 2020 | SPC-1128<br>Version 4 |

| Lot                                                                                   | Use                | Manufacturer | Filling Line          | DOM         | Specification         |
|---------------------------------------------------------------------------------------|--------------------|--------------|-----------------------|-------------|-----------------------|
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) | Comparability, PPQ | Catalent     | Flexible Filling Line | 26 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) | Comparability, PPQ | Catalent     | Flexible Filling Line | 10 Dec 2020 | SPC-1128<br>Version 4 |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) | Comparability, PPQ | Catalent     | Vial Line (b)(4)      | 25 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) | Comparability, PPQ | Catalent     | Vial Line             | 28 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) | Comparability, PPQ | Catalent     | Vial Line             | 30 Nov 2020 | SPC-1128<br>Version 4 |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) | Comparability, PPQ | Catalent     | Vial Line             | 09 Dec 2020 | SPC-1128<br>Version 4 |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) | Comparability, PPQ | Catalent     | Vial Line             | 01 Jan 2021 | SPC-1128<br>Version 4 |

Abbreviations: DOM = date of manufacture; LDP = labeled drug product; PPQ = process performance qualification; UDP = unlabeled drug product

**Table 2: Comparative Batch Analysis – mRNA-1273 Drug Product 6.3 mL Registration Lots – In Vitro Translation, RNA Content, Purity, RNA Encapsulation, Particle Size, and Polydispersity**

| Lot                                                                                       | <i>In Vitro</i><br>Translation/<br>Methionine<br>Labelling (kDa) | RNA Content<br>(mg/mL)<br>by AEX-HPLC | Purity<br>(%Main Peak Area)<br>by RP-HPLC | RNA Encapsulation<br>(%)<br>by (b) (4) | Particle size (nm)<br>by Dynamic Light<br>Scattering | Polydispersity<br>by Dynamic Light<br>Scattering |
|-------------------------------------------------------------------------------------------|------------------------------------------------------------------|---------------------------------------|-------------------------------------------|----------------------------------------|------------------------------------------------------|--------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                               | (b) (4)                                                          |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |

| Lot                                                                                   | <i>In Vitro</i><br>Translation/<br>Methionine<br>Labelling (kDa) | RNA Content<br>(mg/mL)<br>by AEX-HPLC | Purity<br>(%Main Peak Area)<br>by RP-HPLC | RNA Encapsulation<br>(%)<br>by (b) (4) | Particle size (nm)<br>by Dynamic Light<br>Scattering | Polydispersity<br>by Dynamic Light<br>Scattering |
|---------------------------------------------------------------------------------------|------------------------------------------------------------------|---------------------------------------|-------------------------------------------|----------------------------------------|------------------------------------------------------|--------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                           | (b) (4)                                                          |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) |                                                                  |                                       |                                           |                                        |                                                      |                                                  |

Abbreviations: AEX = anion exchange; HPLC = high-performance liquid chromatography; LDP = labeled drug product; RP = reverse phase; UDP = unlabeled drug product

<sup>a</sup> Percent RNA Encapsulation was performed by (b) (4) for this lot.

<sup>b</sup> Particle size specification was (b) (4) for this lot.

**Table 3: Comparative Batch Analysis – mRNA-1273 Drug Product 6.3 mL Registration Lots – Identity**

| Lot                                                                                       | Identity<br>by Reverse Transcription Sanger Sequencing | Lipid Identification<br>by HPLC-CAD |             |      |             |
|-------------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------|-------------|------|-------------|
| Acceptance Criteria:                                                                      | (b) (4)                                                | SM-102                              | Cholesterol | DSPC | PEG2000-DMG |
| (b) (4)                                                                                   | (b) (4)                                                | (b) (4)                             |             |      |             |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) | Conforms                                               | Conforms                            |             |      |             |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A)     | Conforms                                               | Conforms                            |             |      |             |



| Lot                                                                                   | Identity<br>by Reverse Transcription Sanger Sequencing | Lipid Identification<br>by HPLC-CAD |             |      |             |
|---------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------|-------------|------|-------------|
|                                                                                       |                                                        | SM-102                              | Cholesterol | DSPC | PEG2000-DMG |
| Acceptance Criteria:                                                                  | (b) (4)                                                | (b) (4)                             |             |      |             |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) | Conforms                                               |                                     |             |      |             |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) | Conforms                                               |                                     |             |      |             |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) | Conforms                                               |                                     |             |      |             |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) | Conforms                                               |                                     |             |      |             |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) | Conforms                                               |                                     |             |      |             |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) | Conforms                                               |                                     |             |      |             |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) | Conforms                                               |                                     |             |      |             |

Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LDP = labeled drug product; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 4: Comparative Batch Analysis – mRNA-1273 Drug Product 6.3 mL Registration Lots – Lipid Content**

| Lot                                                                                       | Lipid Content (mg/mL) by HPLC-CAD |             |      |             |
|-------------------------------------------------------------------------------------------|-----------------------------------|-------------|------|-------------|
| Acceptance Criteria:                                                                      | SM-102                            | Cholesterol | DSPC | PEG2000-DMG |
| (b) (4)                                                                                   |                                   |             |      |             |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     |                                   |             |      |             |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     |                                   |             |      |             |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) |                                   |             |      |             |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     |                                   |             |      |             |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     |                                   |             |      |             |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) |                                   |             |      |             |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     |                                   |             |      |             |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) |                                   |             |      |             |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A)     |                                   |             |      |             |

| Lot                                                                                   | Lipid Content (mg/mL) by HPLC-CAD |             |      |             |
|---------------------------------------------------------------------------------------|-----------------------------------|-------------|------|-------------|
|                                                                                       | SM-102                            | Cholesterol | DSPC | PEG2000-DMG |
| Acceptance Criteria:                                                                  | (b) (4)                           |             |      |             |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) |                                   |             |      |             |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) |                                   |             |      |             |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) |                                   |             |      |             |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) |                                   |             |      |             |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) |                                   |             |      |             |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) |                                   |             |      |             |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) |                                   |             |      |             |

Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LDP = labeled drug product; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 5: Comparative Batch Analysis – mRNA-1273 Drug Product 6.3 mL Registration Lots – Appearance, Container Content, and Particulate Matter**

| Lot                                                                                       | Appearance by Visual Inspection                                                                                      | Container Content (mL)<br>by USP <697> | Particulate Matter<br>(Particulates Per Container)<br>by USP <788> Method 2 |
|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------------------------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                               | <b>White to off-white dispersion<br/>May contain visible, white or translucent<br/>product-related particulates.</b> | (b) (4)                                |                                                                             |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |

| Lot                                                                                   | Appearance by Visual Inspection                                                                                      | Container Content (mL)<br>by USP <697> | Particulate Matter<br>(Particulates Per Container)<br>by USP <788> Method 2 |
|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------------------------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                           | <b>White to off-white dispersion<br/>May contain visible, white or translucent<br/>product-related particulates.</b> | (b) (4)                                |                                                                             |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                                        |                                                                             |

Abbreviations: LDP = labeled drug product; UDP = unlabeled drug product

**Table 6: Comparative Batch Analysis – mRNA-1273 Drug Product 6.3 mL Registration Lots – pH, Osmolality, Sterility, and Bacterial Endotoxins**

| Lot                                                                                       | pH<br>by USP <791> | Osmolality (mOsm/kg)<br>by USP <785><br>Freezing Point Depression | Sterility<br>by USP <71>,<br>Ph. Eur. 2.6.1 | Bacterial Endotoxins<br>(EU/mL)<br>by USP <85>,<br>Ph. Eur. 2.6.14 |
|-------------------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------|---------------------------------------------|--------------------------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                               | (b) (4)            |                                                                   |                                             |                                                                    |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     |                    |                                                                   |                                             |                                                                    |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     |                    |                                                                   |                                             |                                                                    |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     |                    |                                                                   |                                             |                                                                    |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     |                    |                                                                   |                                             |                                                                    |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     |                    |                                                                   |                                             |                                                                    |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) |                    |                                                                   |                                             |                                                                    |

| Lot                                                                                   | pH<br>by USP <791> | Osmolality (mOsm/kg)<br>by USP <785><br>Freezing Point Depression | Sterility<br>by USP <71>,<br>Ph. Eur. 2.6.1 | Bacterial Endotoxins<br>(EU/mL)<br>by USP <85>,<br>Ph. Eur. 2.6.14 |
|---------------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------|---------------------------------------------|--------------------------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                           | (b) (4)            |                                                                   |                                             |                                                                    |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) |                    |                                                                   |                                             |                                                                    |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) |                    |                                                                   |                                             |                                                                    |

Abbreviations: EU = endotoxin unit(s); LDP = labeled drug product; UDP = unlabeled drug product

<sup>a</sup> USP <85> was not included in Bacterial Endotoxins method description, at time of lot UDP: 6007320005 release.

**Table 7: Comparative Batch Analysis – mRNA-1273 Drug Product 6.3 mL Registration Lots – Impurities**

| Lot                                                                                       | Product-Related Impurities<br>(%Peak Area) by RP-HPLC | Lipid Impurities (%Area) by HPLC-CAD |       |       |         |       |       |
|-------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------|-------|-------|---------|-------|-------|
| Acceptance Criteria:                                                                      | (b) (4)                                               |                                      |       |       |         |       |       |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     | (b) (4)                                               | ND                                   | ND    | ND    | (b) (4) | ND    | ND    |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     |                                                       | ND                                   | ND    | ND    | ND      | < LOQ | < LOQ |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) |                                                       | ND                                   | ND    | ND    | ND      | < LOQ | < LOQ |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     |                                                       | ND                                   | ND    | ND    | ND      | < LOQ | < LOQ |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     |                                                       | ND                                   | < LOQ | ND    | ND      | ND    | ND    |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) |                                                       | ND                                   | ND    | ND    | ND      | < LOQ | < LOQ |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     |                                                       | ND                                   | ND    | < LOQ | ND      | ND    | ND    |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) |                                                       | ND                                   | ND    | < LOQ | ND      | ND    | ND    |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A)     |                                                       | ND                                   | < LOQ | ND    | ND      | ND    | ND    |



| Lot                                                                                   | Product-Related Impurities<br>(%Peak Area) by RP-HPLC | Lipid Impurities (%Area) by HPLC-CAD |       |    |    |    |    |    |
|---------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------|-------|----|----|----|----|----|
| Acceptance Criteria:                                                                  | (b) (4)                                               |                                      |       |    |    |    |    |    |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) | (b) (4)                                               | ND                                   | < LOQ | ND | ND | ND | ND | ND |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) |                                                       | ND                                   | < LOQ | ND | ND | ND | ND | ND |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) |                                                       | < LOQ                                | ND    | ND | ND | ND | ND | ND |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) |                                                       | ND                                   | < LOQ | ND | ND | ND | ND | ND |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) |                                                       | ND                                   | < LOQ | ND | ND | ND | ND | ND |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) |                                                       | ND                                   | < LOQ | ND | ND | ND | ND | ND |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) |                                                       | ND                                   | < LOQ | ND | ND | ND | ND | ND |

Abbreviations: IG = impurity group; LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; RP-HPLC = reverse phase-high performance liquid chromatography; (b) (4); UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 7 Continued (Retention Times above 1.10)**

| Lot                                                                                       | Lipid Impurities (%Area) by HPLC-CAD |    |         |       |       |       |       |       |
|-------------------------------------------------------------------------------------------|--------------------------------------|----|---------|-------|-------|-------|-------|-------|
| Acceptance Criteria:                                                                      | (b) (4)                              |    |         |       |       |       |       |       |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     | ND                                   | ND | (b) (4) | ND    | ND    | ND    | ND    | ND    |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     | ND                                   | ND | ND      | ND    | ND    | < LOQ | ND    | ND    |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) | ND                                   | ND | ND      | < LOQ | ND    | < LOQ | ND    | ND    |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     | ND                                   | ND | ND      | ND    | < LOQ | ND    | ND    | ND    |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     | < LOQ                                | ND | ND      | ND    | ND    | ND    | ND    | < LOQ |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) | ND                                   | ND | ND      | ND    | < LOQ | ND    | ND    | ND    |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     | ND                                   | ND | < LOQ   | ND    | ND    | ND    | < LOQ | ND    |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) | ND                                   | ND | < LOQ   | ND    | ND    | ND    | < LOQ | ND    |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A)     | < LOQ                                | ND | ND      | ND    | ND    | ND    | ND    | < LOQ |

| Lot                                                                                   | Lipid Impurities (%Area) by HPLC-CAD |       |    |    |    |       |       |       |
|---------------------------------------------------------------------------------------|--------------------------------------|-------|----|----|----|-------|-------|-------|
| Acceptance Criteria:                                                                  | (b) (4)                              |       |    |    |    |       |       |       |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) | < LOQ                                | ND    | ND | ND | ND | ND    | ND    | < LOQ |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) | ND                                   | < LOQ | ND | ND | ND | ND    | < LOQ | ND    |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) | < LOQ                                | ND    | ND | ND | ND | < LOQ | ND    | < LOQ |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) | < LOQ                                | ND    | ND | ND | ND | ND    | ND    | < LOQ |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) | < LOQ                                | ND    | ND | ND | ND | ND    | ND    | < LOQ |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) | < LOQ                                | ND    | ND | ND | ND | ND    | ND    | < LOQ |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 700650036<br>(Catalent lot 030M20A)  | ND                                   | < LOQ | ND | ND | ND | ND    | ND    | < LOQ |

Abbreviations: IG = impurity group; LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; (b) (4) ;  
UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 7 Continued (Retention Times above 1.53)**

| Lot                                                                                       | Lipid Impurities (%Area) by HPLC-CAD |    |         |       |       |         |       |         |       |         |
|-------------------------------------------------------------------------------------------|--------------------------------------|----|---------|-------|-------|---------|-------|---------|-------|---------|
| Acceptance Criteria:                                                                      | (b) (4)                              |    |         |       |       |         |       |         |       |         |
| UDP: 6007320005<br>(Catalent lot 011J20)<br>LDP: 7006520005<br>(Catalent lot 011J20A)     | ND                                   | ND | (b) (4) | ND    | ND    | (b) (4) | ND    | (b) (4) | ND    | (b) (4) |
| UDP: 6007920001<br>(Catalent lot 025J20)<br>LDP: 7006520006<br>(Catalent lot 025J20A)     | ND                                   | ND | ND      | ND    | < LOQ | ND      | < LOQ | ND      | < LOQ | < LOQ   |
| UDP: 6007920002<br>(Catalent lot 025J20-2)<br>LDP: 7006520007<br>(Catalent lot 025J20-2A) | ND                                   | ND | ND      | ND    | < LOQ | ND      | < LOQ | ND      | < LOQ | < LOQ   |
| UDP: 6007320006<br>(Catalent lot 029K20)<br>LDP: 7006520008<br>(Catalent lot 029K20A)     | ND                                   | ND | ND      | ND    | < LOQ | ND      | < LOQ | < LOQ   | ND    | < LOQ   |
| UDP: 6007320012<br>(Catalent lot 011L20)<br>LDP: 7006520017<br>(Catalent lot 011L20A)     | ND                                   | ND | < LOQ   | ND    | ND    | ND      | < LOQ | ND      | ND    | < LOQ   |
| UDP: 6007320007<br>(Catalent lot 029K20-2)<br>LDP: 7006520009<br>(Catalent lot 029K20-2A) | ND                                   | ND | ND      | ND    | < LOQ | ND      | < LOQ | < LOQ   | ND    | < LOQ   |
| UDP: 6007320008<br>(Catalent lot 039K20)<br>LDP: 7006520010<br>(Catalent lot 039K20A)     | < LOQ                                | ND | ND      | < LOQ | ND    | ND      | ND    | ND      | ND    | < LOQ   |
| UDP: 6007320009<br>(Catalent lot 039K20-2)<br>LDP: 7006520011<br>(Catalent lot 039K20-2A) | < LOQ                                | ND | ND      | < LOQ | ND    | ND      | ND    | ND      | ND    | < LOQ   |
| UDP: 6007320010<br>(Catalent lot 037K20)<br>LDP: 7006520012<br>(Catalent lot 037K20A)     | ND                                   | ND | < LOQ   | ND    | ND    | ND      | < LOQ | ND      | ND    | < LOQ   |

| Lot                                                                                   | Lipid Impurities (%Area) by HPLC-CAD |       |       |    |    |       |       |    |    |       |
|---------------------------------------------------------------------------------------|--------------------------------------|-------|-------|----|----|-------|-------|----|----|-------|
| Acceptance Criteria:                                                                  | (b) (4)                              |       |       |    |    |       |       |    |    |       |
| UDP: 6007320011<br>(Catalent lot 038K20)<br>LDP: 7006520014<br>(Catalent lot 038K20A) | ND                                   | ND    | < LOQ | ND | ND | ND    | < LOQ | ND | ND | < LOQ |
| UDP: 6007920003<br>(Catalent lot 004M20)<br>LDP: 7006520024<br>(Catalent lot 004M20A) | ND                                   | < LOQ | ND    | ND | ND | < LOQ | N/A   | ND | ND | < LOQ |
| UDP: 6008620001<br>(Catalent lot 025L20)<br>LDP: 7006520013<br>(Catalent lot 025L20A) | ND                                   | < LOQ | ND    | ND | ND | ND    | ND    | ND | ND | < LOQ |
| UDP: 6008620002<br>(Catalent lot 026L20)<br>LDP: 7006520015<br>(Catalent lot 026L20A) | ND                                   | ND    | < LOQ | ND | ND | ND    | < LOQ | ND | ND | < LOQ |
| UDP: 6008620003<br>(Catalent lot 027L20)<br>LDP: 7006520016<br>(Catalent lot 027L20A) | ND                                   | ND    | < LOQ | ND | ND | ND    | < LOQ | ND | ND | < LOQ |
| UDP: 6008620007<br>(Catalent lot 028L20)<br>LDP: 7006520023<br>(Catalent lot 028L20A) | ND                                   | ND    | < LOQ | ND | ND | ND    | < LOQ | ND | ND | < LOQ |
| UDP: 6008520001<br>(Catalent lot 030M20)<br>LDP: 7006520036<br>(Catalent lot 030M20A) | ND                                   | ND    | < LOQ | ND | ND | ND    | < LOQ | ND | ND | < LOQ |

Abbreviations: IG = impurity group; LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; (b) (4) ;

UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 8: Comparative Batch Analysis – mRNA-1273 Drug Product Registration Lots - 8.0 mL Image**

| Lot                                                                                   | Use                | Manufacturer | Filling Line          | DOM         | Specification      |
|---------------------------------------------------------------------------------------|--------------------|--------------|-----------------------|-------------|--------------------|
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) | Comparability, PPQ | Catalent     | Flexible Filling Line | 28 Feb 2021 | SPC-1366 Version 2 |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) | Comparability, PPQ | Catalent     | Vial Line (b)(4)      | 26 Feb 2021 | SPC-1366 Version 2 |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) | Comparability, PPQ | Catalent     | Vial Line             | 01 May 2021 | SPC-1366 Version 3 |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) | Comparability, PPQ | Catalent     | Vial Line             | 27 Apr 2021 | SPC-1366 Version 3 |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) | Comparability, PPQ | Catalent     | Vial Line             | 30 Apr 2021 | SPC-1366 Version 3 |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      | Comparability, PPQ | Baxter       | Vial Line             | 27 Mar 2021 | SPC-1353 Version 1 |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      | Comparability, PPQ | Baxter       | Vial Line             | 02 Apr 2021 | SPC-1353 Version 1 |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      | Comparability, PPQ | Baxter       | Vial Line             | 06 Apr 2021 | SPC-1353 Version 1 |

Abbreviations: DOM = date of manufacture; LDP = labeled drug product; PPQ = process performance qualification; UDP = unlabeled drug product

**Table 9: Comparative Batch Analysis – mRNA-1273 Drug Product 8.0 mL Registration Lots – In Vitro Translation, RNA Content, Purity, RNA Encapsulation, Particle Size, and Polydispersity**

| Lot                                                                                   | <i>In Vitro</i><br>Translation/<br>Methionine<br>Labelling (kDa) | RNA Content<br>(mg/mL) by AEX-<br>HPLC | Purity<br>(%Main Peak<br>Area)<br>by RP-HPLC | RNA<br>Encapsulation (%)<br>by (b) (4) | Filtered Mean<br>Particle size (nm)<br>by Dynamic Light<br>Scattering | Polydispersity by<br>Dynamic Light<br>Scattering |
|---------------------------------------------------------------------------------------|------------------------------------------------------------------|----------------------------------------|----------------------------------------------|----------------------------------------|-----------------------------------------------------------------------|--------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                           | (b) (4)                                                          |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      |                                                                  |                                        |                                              |                                        |                                                                       |                                                  |

Abbreviations: AEX = anion exchange; HPLC = high-performance liquid chromatography; LDP = labeled drug product; RP = reverse phase; UDP = unlabeled drug product

**Table 10: Comparative Batch Analysis – mRNA-1273 Drug Product 8.0 mL Registration Lots – Identity**

| Lot                                                                                   | Identity by Reverse Transcription Sanger Sequencing | Lipid Identification by HPLC-CAD |             |      |             |
|---------------------------------------------------------------------------------------|-----------------------------------------------------|----------------------------------|-------------|------|-------------|
|                                                                                       |                                                     | SM-102                           | Cholesterol | DSPC | PEG2000-DMG |
| Acceptance Criteria:                                                                  | (b) (4)                                             | (b) (4)                          |             |      |             |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      | Conforms                                            | Conforms                         |             |      |             |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      | Conforms                                            | Conforms                         |             |      |             |

Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LDP = labeled drug product; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection



**Table 11: Comparative Batch Analysis – mRNA-1273 Drug Product 8.0 mL Registration Lots –Lipid Content**

| Lot                                                                                   | Lipid Content (mg/mL) by HPLC-CAD |             |      |             |
|---------------------------------------------------------------------------------------|-----------------------------------|-------------|------|-------------|
| Acceptance Criteria:                                                                  | SM-102                            | Cholesterol | DSPC | PEG2000-DMG |
| (b) (4)                                                                               |                                   |             |      |             |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) |                                   |             |      |             |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) |                                   |             |      |             |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) |                                   |             |      |             |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) |                                   |             |      |             |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) |                                   |             |      |             |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      |                                   |             |      |             |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      |                                   |             |      |             |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      |                                   |             |      |             |

Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LDP = labeled drug product; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 12: Comparative Batch Analysis – mRNA-1273 Drug Product 8.0 mL Registration Lots – Appearance, Container Content, and Particulate Matter**

| Lot                                                                                   | Appearance by Visual Inspection                                                                                      | Container Content (mL) | Particulate Matter<br>(Particulates Per Container)<br>by USP <788> Method 2 |
|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|------------------------|-----------------------------------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                           | <b>White to off-white dispersion<br/>May contain visible, white or translucent<br/>product-related particulates.</b> | (b) (4)                |                                                                             |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      | White to off-white dispersion<br>Essentially free of particulates                                                    |                        |                                                                             |

Abbreviations: LDP = labeled drug product; UDP = unlabeled drug product

**Table 13: Comparative Batch Analysis – mRNA-1273 Drug Product 8.0 mL Registration Lots – pH, Osmolality, Sterility, and Bacterial Endotoxins**

| Lot                                                                                   | pH<br>by USP <791> | Osmolality (mOsm/kg)<br>by USP <785><br>Freezing Point Depression | Sterility<br>by USP <71>, Ph. Eur. 2.6.1 | Bacterial Endotoxins<br>(EU/mL)<br>by USP <85>, Ph. Eur. 2.6.14 |
|---------------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------|------------------------------------------|-----------------------------------------------------------------|
| <b>Acceptance Criteria:</b>                                                           | (b) (4)            |                                                                   |                                          |                                                                 |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) |                    |                                                                   |                                          |                                                                 |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) |                    |                                                                   |                                          |                                                                 |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) |                    |                                                                   |                                          |                                                                 |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) |                    |                                                                   |                                          |                                                                 |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) |                    |                                                                   |                                          |                                                                 |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      |                    |                                                                   |                                          |                                                                 |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      |                    |                                                                   |                                          |                                                                 |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      |                    |                                                                   |                                          |                                                                 |

Abbreviations: EU = endotoxin unit(s); LDP = labeled drug product; UDP = unlabeled drug product

**Table 14: Comparative Batch Analysis – mRNA-1273 Drug Product 8.0 mL Registration Lots – Impurities**

| Lot                                                                                   | Product-Related Impurities<br>(%Peak Area) by RP-HPLC | Lipid Impurities (%Area) by HPLC-CAD |       |      |       |       |         |       |       |       |       |
|---------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------|-------|------|-------|-------|---------|-------|-------|-------|-------|
|                                                                                       |                                                       | Individual                           |       |      |       |       |         |       |       |       |       |
| Acceptance Criteria:                                                                  | (b) (4)                                               |                                      |       |      |       |       |         |       |       |       |       |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) | (b) (4)                                               | ND                                   | < LOQ | ND   | ND    | < LOQ | ND      | ND    | < LOQ | ND    | ND    |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) |                                                       | ND                                   | < LOQ | ND   | ND    | ND    | ND      | ND    | < LOQ | ND    | ND    |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) |                                                       | < LOQ                                | ND    | ND   | < LOQ | ND    | ND      | < LOQ | ND    | < LOQ | < LOQ |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) |                                                       | < LOQ                                | ND    | ND   | < LOQ | ND    | (b) (4) | ND    | ND    | ND    | ND    |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) |                                                       | < LOQ                                | ND    | ND   | < LOQ | ND    |         | ND    | ND    | ND    | ND    |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      |                                                       | ND                                   | ND    | <LOQ | ND    | ND    | ND      | ND    | ND    | < LOQ | ND    |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      |                                                       | < LOQ                                | ND    | ND   | ND    | ND    | < LOQ   | ND    | ND    | ND    | ND    |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      |                                                       | < LOQ                                | ND    | ND   | ND    | ND    | < LOQ   | ND    | ND    | ND    | ND    |

Abbreviations: IG = impurity group; LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; RP-HPLC = reverse phase-high-performance liquid chromatography; (b) (4) ; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 14 Continued (Retention Times above 1.49)**

| Lot                                                                                   | Lipid Impurities (% Area) by HPLC-CAD |         |       |       |       |       |       |       |       |       |       |         |
|---------------------------------------------------------------------------------------|---------------------------------------|---------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|
|                                                                                       | (b) (4)                               |         |       |       |       |       |       |       |       |       |       |         |
| <b>Acceptance Criteria:</b>                                                           |                                       |         |       |       |       |       |       |       |       |       |       |         |
| UDP: 6009821002<br>(Catalent lot 022B21)<br>LDP: 7007621001<br>(Catalent lot 022B21A) | ND                                    | ND      | < LOQ | ND    | ND    | ND    | ND    | ND    | ND    | ND    | ND    | < LOQ   |
| UDP: 6010121002<br>(Catalent lot 033B21)<br>LDP: 7007621002<br>(Catalent lot 033B21A) | ND                                    | ND      | < LOQ | ND    | ND    | < LOQ | ND    | ND    | < LOQ | ND    | ND    | < LOQ   |
| UDP: 6009921006<br>(Catalent lot 038D21)<br>LDP: 7007621030<br>(Catalent lot 038D21A) | < LOQ                                 | (b) (4) | ND    | < LOQ | < LOQ | ND    | ND    | < LOQ | ND    | ND    | ND    | (b) (4) |
| UDP: 6003921002<br>(Catalent lot 047D21)<br>LDP: 7007621077<br>(Catalent lot 047D21A) | ND                                    | < LOQ   | ND    | ND    | < LOQ | ND    | < LOQ | N/A   | ND    | ND    | ND    |         |
| UDP: 6010121003<br>(Catalent lot 054D21)<br>LDP: 7007621041<br>(Catalent lot 054D21A) | ND                                    | < LOQ   | ND    | ND    | < LOQ | ND    | < LOQ | ND    | ND    | ND    | ND    |         |
| UDP: 6008221002<br>(Baxter lot 939596)<br>LDP: 7007621003<br>(Baxter lot 939599)      | ND                                    | ND      | ND    | ND    | ND    | ND    | ND    | ND    | ND    | < LOQ | < LOQ | < LOQ   |
| UDP: 6008221003<br>(Baxter lot 939597)<br>LDP: 7007621004<br>(Baxter lot 939600)      | < LOQ                                 | ND      | < LOQ | ND    | < LOQ | ND    | ND    | ND    | ND    | ND    | ND    | < LOQ   |
| UDP: 6008921001<br>(Baxter lot 939675)<br>LDP: 7007621005<br>(Baxter lot 939676)      | < LOQ                                 | ND      | ND    | < LOQ | < LOQ | ND    | ND    | ND    | ND    | ND    | ND    | < LOQ   |

Abbreviations: IG = impurity group; LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; RP-HPLC = reverse-phase high-performance liquid chromatography; (b) (4); UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

**Table 15: mRNA-1273 Drug Product Clinical Lots**

| Lot                                                                  | Use     | Scale       | Manufacturer | DOM         | Specification      |
|----------------------------------------------------------------------|---------|-------------|--------------|-------------|--------------------|
| 8520100101                                                           | Phase 1 | PVU Process | Moderna      | 07 Feb 2020 | SPC-0948 Version 2 |
| 8520100102                                                           | Phase 2 | PVU Process | Moderna      | 19 Mar 2020 | SPC-0948 Version 3 |
| 8520100103                                                           | Phase 2 | PVU Process | Moderna      | 23 Mar 2020 | SPC-0948 Version 3 |
| 8520100104                                                           | Phase 2 | PVU Process | Moderna      | 02 Apr 2020 | SPC-0948 Version 3 |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    | Phase 2 | Scale A     | Moderna      | 28 May 2020 | SPC-1063 Version 1 |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    | Phase 3 | Scale A     | Moderna      | 02 Jun 2020 | SPC-1063 Version 1 |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 | Phase 3 | Scale A     | Moderna      | 04 Jun 2020 | SPC-1063 Version 1 |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    | Phase 3 | Scale A     | Moderna      | 25 Jun 2020 | SPC-1063 Version 2 |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    | Phase 3 | Scale A     | Moderna      | 30 Jun 2020 | SPC-1063 Version 2 |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    | Phase 3 | Scale A     | Moderna      | 08 Jul 2020 | SPC-1063 Version 2 |

Abbreviations: DOM = date of manufacture; LDP = labeled drug product; PPQ = process performance qualification; PVU = personalized vaccine unit;  
UDP = unlabeled drug product

<sup>a</sup> Pivotal Phase 3 clinical study lots.

**Table 16: Comparative Batch Analysis – mRNA-1273 Drug Product Clinical Lots – In Vitro Translation, RNA Content, Purity, RNA Encapsulation, Particle Size, and Polydispersity**

| Lot                                                                  | Potency (kDa) by<br><i>In Vitro</i><br>Translation/<br>Methionine<br>Labelling | RNA Content<br>(mg/mL) by AEX-<br>HPLC | Purity<br>(% Main Peak<br>Area)<br>by RP-HPLC | RNA<br>Encapsulation (%)<br>by (b) (4) | Particle size (nm)<br>by Dynamic Light<br>Scattering | Polydispersity by<br>Dynamic Light<br>Scattering |
|----------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------|-----------------------------------------------|----------------------------------------|------------------------------------------------------|--------------------------------------------------|
| Acceptance Criteria:                                                 | (b) (4)                                                                        |                                        |                                               |                                        |                                                      |                                                  |
| 8520100101                                                           | N/A <sup>(b)</sup>                                                             |                                        |                                               |                                        |                                                      |                                                  |
| 8520100102                                                           | (b) (4)                                                                        |                                        |                                               |                                        |                                                      |                                                  |
| 8520100103                                                           |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| 8520100104                                                           |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    |                                                                                |                                        |                                               |                                        |                                                      |                                                  |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    |                                                                                |                                        |                                               |                                        |                                                      |                                                  |

Abbreviations: AEX = anion exchange chromatography; HPLC = high-performance liquid chromatography; LDP = labeled drug product; RP = reverse phase;

UDP =unlabeled drug product

<sup>a</sup> Pivotal Phase 3 clinical study lots.

<sup>b</sup> Test not present on specification for this lot.

<sup>c</sup> RNA Content specification was (b) (4) for these lots.

<sup>d</sup> Purity specification was (b) (4) for these lots.

<sup>e</sup> Polydispersity specification was (b) (4) for these lots.

**Table 17: Comparative Batch Analysis – mRNA-1273 Drug Product Clinical Lots – Identity**

| Lot                                                                  | Identity by Reverse Transcription<br>Sanger Sequencing | Lipid Identification by HPLC-CAD |             |      |                 |
|----------------------------------------------------------------------|--------------------------------------------------------|----------------------------------|-------------|------|-----------------|
|                                                                      |                                                        | SM-102                           | Cholesterol | DSPC | PEG2000-<br>DMG |
| Acceptance Criteria:                                                 | (b) (4)                                                | (b) (4)                          |             |      |                 |
| 8520100101                                                           | Conforms <sup>(b)</sup>                                | Conforms                         |             |      |                 |
| 8520100102                                                           | Conforms <sup>(b)</sup>                                | Conforms                         |             |      |                 |
| 8520100103                                                           | Conforms <sup>(b)</sup>                                | Conforms                         |             |      |                 |
| 8520100104                                                           | Conforms <sup>(b)</sup>                                | Conforms                         |             |      |                 |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    | Conforms                                               | Conforms                         |             |      |                 |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    | Conforms                                               | Conforms                         |             |      |                 |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 | Conforms                                               | Conforms                         |             |      |                 |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    | Conforms                                               | Conforms                         |             |      |                 |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    | Conforms                                               | Conforms                         |             |      |                 |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    | Conforms                                               | Conforms                         |             |      |                 |

Abbreviations: Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LDP = labeled drug product; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

<sup>a</sup> Pivotal Phase 3 clinical study lots.

<sup>b</sup> Identity specification was (b) (4) for these lots



**Table 18: Comparative Batch Analysis – mRNA-1273 Drug Product Clinical Lots – Lipid Content**

| Lot                                                                  | Lipid Content (mg/mL) by HPLC-CAD |             |      |             |
|----------------------------------------------------------------------|-----------------------------------|-------------|------|-------------|
| Acceptance Criteria:                                                 | SM-102                            | Cholesterol | DSPC | PEG2000-DMG |
| (b) (4)                                                              |                                   |             |      |             |
| 8520100101                                                           |                                   |             |      |             |
| 8520100102                                                           |                                   |             |      |             |
| 8520100103                                                           |                                   |             |      |             |
| 8520100104                                                           |                                   |             |      |             |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    |                                   |             |      |             |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    |                                   |             |      |             |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 |                                   |             |      |             |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    |                                   |             |      |             |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    |                                   |             |      |             |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    |                                   |             |      |             |

Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LDP = labeled drug product; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

<sup>a</sup> Pivotal Phase 3 clinical study lots.

<sup>b</sup> Lipid Identification specifications are (b) (4) for these lots.

**Table 19: Comparative Batch Analysis – mRNA-1273 Drug Product Clinical Lots - Appearance, Container Content, and Particulate Matter**

| Lot                                                                  | Appearance<br>by Visual Inspection                                                                          | Container Content (mL)<br>by USP <697> | Particulate Matter<br>(Particulates Per Container)<br>by USP <788> Method 2 |
|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------------------------------------------------------------------|
| Acceptance Criteria:                                                 | White to off-white dispersion<br>May contain visible, white or translucent<br>product-related particulates. | (b) (4)                                | (b) (4)                                                                     |
| 8520100101                                                           | White to off-white dispersion<br>Essentially free of particulates                                           | N/A <sup>(b)</sup>                     |                                                                             |
| 8520100102                                                           | White to off-white dispersion<br>Essentially free of particulates                                           | N/A <sup>(b)</sup>                     |                                                                             |
| 8520100103                                                           | White to off-white dispersion<br>Essentially free of particulates                                           | N/A <sup>(b)</sup>                     |                                                                             |
| 8520100104 Criteria                                                  | White to off-white dispersion<br>Essentially free of particulates                                           | N/A <sup>(b)</sup>                     |                                                                             |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    | White to off-white dispersion<br>Essentially free of particulates                                           | (b) (4)                                |                                                                             |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    | White to off-white dispersion<br>Essentially free of particulates                                           |                                        |                                                                             |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 | White to off-white dispersion<br>Essentially free of particulates                                           |                                        |                                                                             |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    | White to off-white dispersion<br>Essentially free of particulates                                           |                                        |                                                                             |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    | White to off-white dispersion<br>Essentially free of particulates                                           |                                        |                                                                             |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    | White to off-white dispersion<br>Essentially free of particulates                                           |                                        |                                                                             |

Abbreviations: LDP = labeled drug product; N/A = not applicable; UDP = unlabeled drug product

<sup>a</sup> Pivotal Phase 3 clinical study lots.

<sup>b</sup> Test not present on specification for these lots.

**Table 20: Comparative Batch Analysis – mRNA-1273 Drug Product Clinical Lots – pH, Osmolality, Sterility, and Bacterial Endotoxins**

| Lot                                                                  | pH<br>by USP <791> | Osmolality (mOsm/kg)<br>by USP <785><br>Freezing Point Depression | Sterility<br>by USP <71>,<br>Ph. Eur. 2.6.1 | Bacterial Endotoxins<br>(EU/mL)<br>by USP <85>,<br>Ph. Eur. 2.6.14 |
|----------------------------------------------------------------------|--------------------|-------------------------------------------------------------------|---------------------------------------------|--------------------------------------------------------------------|
| Acceptance Criteria:                                                 | (b) (4)            |                                                                   |                                             |                                                                    |
| 8520100101                                                           |                    |                                                                   |                                             |                                                                    |
| 8520100102                                                           |                    |                                                                   |                                             |                                                                    |
| 8520100103                                                           |                    |                                                                   |                                             |                                                                    |
| 8520100104                                                           |                    |                                                                   |                                             |                                                                    |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    |                    |                                                                   |                                             |                                                                    |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    |                    |                                                                   |                                             |                                                                    |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 |                    |                                                                   |                                             |                                                                    |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    |                    |                                                                   |                                             |                                                                    |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    |                    |                                                                   |                                             |                                                                    |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    |                    |                                                                   |                                             |                                                                    |

Abbreviations: EU = endotoxin unit(s); LDP = labeled drug product; M = middle, UDP = unlabeled drug product

<sup>a</sup> Pivotal Phase 3 clinical study lots.

<sup>b</sup> Osmolality specification was (b) (4) for these lots.

**Table 21: Comparative Batch Analysis – mRNA-1273 Drug Product Clinical Lots - Impurities**

| Lot                                                                  | Product-Related Impurities<br>(%Peak Area) by RP-HPLC | Lipid Impurities (%Area) by HPLC-CAD |         |     |       |       |         |
|----------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------|---------|-----|-------|-------|---------|
| Acceptance Criteria:                                                 | (b) (4)                                               |                                      |         |     |       |       |         |
| 8520100101                                                           | (b) (4)                                               | ND                                   | ND      | ND  | ND    | ND    | ND      |
| 8520100102                                                           | (b) (4)                                               | ND                                   | ND      | ND  | ND    | ND    | ND      |
| 8520100103                                                           | (b) (4)                                               | ND                                   | ND      | ND  | ND    | < LOQ | ND      |
| 8520100104                                                           | (b) (4)                                               | ND                                   | N/A     | N/A | < LOQ | < LOQ | ND      |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    | (b) (4)                                               | ND                                   | (b) (4) |     |       |       | ND      |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    | (b) (4)                                               | (b) (4)                              | ND      | ND  | ND    | ND    | (b) (4) |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 | (b) (4)                                               | (b) (4)                              | ND      | ND  | ND    | ND    | (b) (4) |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    | (b) (4)                                               | ND                                   | ND      | ND  | ND    | ND    | (b) (4) |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    | (b) (4)                                               | ND                                   | ND      | ND  | ND    | ND    | (b) (4) |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    | (b) (4)                                               | ND                                   | ND      | ND  | ND    | ND    | (b) (4) |

Abbreviations: IG = impurity group; LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; RP-HPLC = reverse-phase high-performance liquid chromatography; (b) (4) ; UDP = unlabeled drug product; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

<sup>a</sup> Pivotal Phase 3 clinical study lots.

**Table 21 Continued (Retention Times above 1.10)**

| Lot                                                                  | Lipid Impurities (% Area) by HPLC-CAD |         |       |         |         |         |         |         |
|----------------------------------------------------------------------|---------------------------------------|---------|-------|---------|---------|---------|---------|---------|
|                                                                      | (b) (4)                               |         |       |         |         |         |         |         |
| Acceptance Criteria:                                                 |                                       |         |       |         |         |         |         |         |
| 8520100101                                                           | ND                                    | ND      | ND    | ND      | ND      | ND      | ND      | ND      |
| 8520100102                                                           | ND                                    | ND      | ND    | ND      | ND      | ND      | ND      | ND      |
| 8520100103                                                           | ND                                    | ND      | ND    | < LOQ   | ND      | ND      | ND      | ND      |
| 8520100104                                                           | ND                                    | ND      | < LOQ | ND      | ND      | ND      | ND      | ND      |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    | ND                                    | ND      | ND    | (b) (4) | ND      | ND      | ND      | ND      |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    | (b) (4)                               | ND      | ND    | ND      | (b) (4) | ND      | (b) (4) | ND      |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 | (b) (4)                               | ND      | ND    | ND      | (b) (4) | ND      | (b) (4) | ND      |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    | ND                                    | (b) (4) | ND    | ND      | N/A     | (b) (4) | ND      | (b) (4) |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    | ND                                    | (b) (4) | ND    | ND      | N/A     | (b) (4) | ND      | (b) (4) |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    | ND                                    | (b) (4) | ND    | ND      | N/A     | (b) (4) | (b) (4) | ND      |

Abbreviations: LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; (b) (4) ; UDP = unlabeled drug product;  
HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

<sup>a</sup> Pivotal Phase 3 clinical study lots.

**Table 21 Continued (Retention Times above 1.60)**

| Lot                                                                  | Lipid Impurities (%Area) by HPLC-CAD |         |       |       |         |    |         |       |
|----------------------------------------------------------------------|--------------------------------------|---------|-------|-------|---------|----|---------|-------|
| Acceptance Criteria:                                                 | (b) (4)                              |         |       |       |         |    |         |       |
| 8520100101                                                           | ND                                   | ND      | ND    | ND    | ND      | ND | ND      | ND    |
| 8520100102                                                           | ND                                   | ND      | ND    | ND    | ND      | ND | ND      | ND    |
| 8520100103                                                           | ND                                   | ND      | ND    | < LOQ | ND      | ND | < LOQ   | < LOQ |
| 8520100104                                                           | < LOQ                                | ND      | < LOQ | ND    | ND      | ND | ND      | < LOQ |
| UDP: 6007520001 <sup>(a)</sup><br>LDP: 7006320001                    | ND                                   | (b) (4) | ND    | ND    | (b) (4) | ND | (b) (4) |       |
| UDP: 6007520002 <sup>(a)</sup><br>LDP: 7006320002                    | (b) (4)                              | ND      | ND    | ND    | ND      | ND | ND      |       |
| UDP: 6007520003 <sup>(a)</sup><br>LDP: 7006320003<br>LDP: 7006320010 |                                      | ND      | ND    | ND    | ND      | ND | ND      |       |
| UDP: 6007520004 <sup>(a)</sup><br>LDP: 7006320004                    | ND                                   | ND      | ND    | ND    | ND      | ND | ND      |       |
| UDP: 6007520005 <sup>(a)</sup><br>LDP: 7006320005                    | ND                                   | ND      | ND    | ND    | ND      | ND | ND      |       |
| UDP: 6007520006 <sup>(a)</sup><br>LDP: 7006320006                    | ND                                   | ND      | ND    | ND    | ND      | ND | ND      |       |

Abbreviations: LDP = labeled drug product; LOQ = limit of quantitation; ND = not detected; (b) (4); UDP = unlabeled drug product;  
HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

<sup>a</sup> Pivotal Phase 3 clinical study lots.

**Table 22: Index of Certificates of Analysis**

| Document Title                                                                                                                       | Document Number                    |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007320005 (Catalent lot 011J20), LDP: 7006520005 (Catalent lot 011J20A)     | <a href="#">COA-0548 Version 3</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007320006 (Catalent lot 029K20), LDP: 7006520008 (Catalent lot 029K20A)     | <a href="#">COA-0598 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007320012 (Catalent lot 011L20), LDP: 7006520017 (Catalent lot 011L20A)     | <a href="#">COA-0615 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007320007 (Catalent lot 029K20-2), LDP: 7006520009 (Catalent lot 029K20-2A) | <a href="#">COA-0599 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007320008 (Catalent lot 039K20), LDP: 7006520010 (Catalent lot 039K20A)     | <a href="#">COA-0605 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007320011 (Catalent lot 038K20), LDP: 7006520014 (Catalent lot 038K20A)     | <a href="#">COA-0601 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007920003 (Catalent lot 004M20), LDP: 7006520024 (Catalent lot 004M20A)     | <a href="#">COA-0643 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007920001 (Catalent lot 025J20), LDP: 7006520006 (Catalent lot 025J20A)     | <a href="#">COA-0571 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007920002 (Catalent lot 025J20-2), LDP: 7006520007 (Catalent lot 025J20-2A) | <a href="#">COA-0572 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008620001 (Catalent lot 025L20), LDP: 7006520013 (Catalent lot 025L20A)     | <a href="#">COA-0606 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008620002 (Catalent lot 026L20), LDP: 7006520015 (Catalent lot 026L20A)     | <a href="#">COA-0607 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008620003 (Catalent lot 027L20), LDP: 7006520016 (Catalent lot 027L20A)     | <a href="#">COA-0613 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008620007 (Catalent lot 028L20), LDP: 7006520023 (Catalent lot 028L20A)     | <a href="#">COA-0640 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008520001 (Catalent lot 030M20), LDP: 7006520036 (Catalent lot 030M20A)     | <a href="#">COA-0714 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6009821002 (Catalent lot 022B21), LDP: 7007621001 (Catalent lot 022B21A)     | <a href="#">COA-0995 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6010121002 (Catalent lot 033B21), LDP: 7007621002 (Catalent lot 033B21A)     | <a href="#">COA-0994 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6009921006 (Catalent lot 038D21) LDP: 7007621030 (Catalent lot 038D21A)      | <a href="#">COA-1461 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6003921002 (Catalent lot 047D21) LDP: 7007621077 (Catalent lot 047D21A)      | <a href="#">COA-1509 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6010121003 (Catalent lot 054D21) LDP: 7007621041 (Catalent lot 054D21A)      | <a href="#">COA-1510 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008221002 (Baxter lot 939596) LDP: 7007621003 (Baxter lot 939599)           | <a href="#">COA-1277 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008221003 (Baxter lot 939597) LDP: 7007621004 (Baxter lot 939600)           | <a href="#">COA-1278 Version 1</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6008921001 (Baxter lot                                                       | <a href="#">COA-1279 Version 1</a> |

| Document Title                                                                      | Document Number                    |
|-------------------------------------------------------------------------------------|------------------------------------|
| 939675) LDP: 7007621005 (Baxter lot 939676)                                         |                                    |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520001, LDP: 7006320001 | <a href="#">COA-0437 Version 4</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520002, LDP: 7006320002 | <a href="#">COA-0438 Version 3</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520003, LDP: 7006320003 | <a href="#">COA-0439 Version 4</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520003, LDP: 7006320010 |                                    |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520004, LDP: 7006320004 | <a href="#">COA-0454 Version 3</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520005, LDP: 7006320005 | <a href="#">COA-0465 Version 4</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520006, LDP: 7006320006 | <a href="#">COA-0466 Version 3</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot 8520100101                       | <a href="#">COA-0363 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot 8520100102                       | <a href="#">COA-0386 Version 2</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot 8520100103                       | <a href="#">COA-0387 Version 3</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot 8520100104                       | <a href="#">COA-0393 Version 4</a> |
| mRNA-1273 Drug Product Certificate of Analysis lot UDP: 6007520007, LDP: 7006320007 | <a href="#">COA-0475 Version 3</a> |