

### 3.2.P.5.1 Specifications

The specification for mRNA-1273 Drug Product is provided in Table 1.

**Table 1: Specification for Drug Product**

| Test                                         | Method                                                 | Method Number                                         | Acceptance Criteria                                                                                                                                              |
|----------------------------------------------|--------------------------------------------------------|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appearance                                   | Visual                                                 | SOP-0278                                              | White to off-white dispersion. May contain visible, white or translucent product-related particulates                                                            |
| Identity                                     | RTSS                                                   | SOP-1032                                              | (b) (4)                                                                                                                                                          |
| Total RNA Content                            | AEX-HPLC                                               | SOP-0999                                              |                                                                                                                                                                  |
| Purity<br>Product-Related Impurities         | RP-IP-HPLC                                             | SOP-0996                                              |                                                                                                                                                                  |
| %RNA Encapsulation                           | (b) (4)                                                | SOP-1000                                              |                                                                                                                                                                  |
| Particle Size                                | DLS                                                    | SOP-0998                                              |                                                                                                                                                                  |
| Polydispersity                               |                                                        |                                                       |                                                                                                                                                                  |
| Lipid (b) (4)                                | HPLC-CAD                                               | SOP-1001                                              |                                                                                                                                                                  |
| SM-102                                       |                                                        |                                                       |                                                                                                                                                                  |
| Cholesterol                                  |                                                        |                                                       |                                                                                                                                                                  |
| DSPC                                         |                                                        |                                                       |                                                                                                                                                                  |
| PEG2000-DMG                                  |                                                        |                                                       |                                                                                                                                                                  |
| Lipid Content (mg/mL)                        | HPLC-CAD                                               | SOP-1001                                              |                                                                                                                                                                  |
| SM-102                                       |                                                        |                                                       |                                                                                                                                                                  |
| Cholesterol                                  |                                                        |                                                       |                                                                                                                                                                  |
| DSPC                                         |                                                        |                                                       |                                                                                                                                                                  |
| PEG2000-DMG                                  |                                                        |                                                       |                                                                                                                                                                  |
| Lipid Impurity                               |                                                        |                                                       |                                                                                                                                                                  |
| Particulate Matter                           |                                                        |                                                       |                                                                                                                                                                  |
| ≥ 25µm particulate matter                    | USP <788>                                              | SOP-0509                                              |                                                                                                                                                                  |
| ≥ 10 µm particulate matter                   | Method 2                                               |                                                       |                                                                                                                                                                  |
| pH                                           | USP <791>                                              | SOP-0288                                              |                                                                                                                                                                  |
| Osmolality – Freezing Point Depression       | USP <785>                                              | SOP-0279                                              |                                                                                                                                                                  |
| In Vitro Translation                         | Cell-Free In Vitro Translation and gel electrophoresis | SOP-0937                                              |                                                                                                                                                                  |
| Container Content                            | Based on USP <697>                                     | SOP-1229 <sup>(a)</sup>                               | <b>Maximum 11 Dose (0.5 mL per dose) Presentation</b><br>Syringe/Needle:<br>Option A: 11 doses of 0.5 mL from 1 vial<br>Option B: 10 doses of 0.5 mL from 1 vial |
|                                              |                                                        |                                                       | <b>Maximum 15 Dose (0.5 mL per dose) Presentation</b><br>Syringe/Needle:<br>Option A: 15 doses of 0.5 mL from 1 vial<br>Option B: 13 doses of 0.5 mL from 1 vial |
| Bacterial Endotoxins                         | USP <85>, Ph. Eur. 2.6.14                              | M_CTS_CS_0929                                         | (b) (4)                                                                                                                                                          |
| Sterility                                    | USP <71>, Ph Eur. 2.6.1                                | A-SOP-09-07-015 and AM-MICRO-256-100-001 or 07-02-003 |                                                                                                                                                                  |
| Container Closure Integrity (stability only) | (b) (4)                                                | 803-TM<br>895-TM                                      |                                                                                                                                                                  |

Abbreviations: AEX-HPLC = anion exchange high-performance liquid chromatography; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; DLS = dynamic light scattering; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; EU = endotoxin unit(s); (b) (4) (b) (4) RP-HPLC = reverse-phase high-performance liquid chromatography; (b) (4) RTSS = reverse transcription Sangar sequencing; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

(b) (4)