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3.2.P.5.2 Analytical Procedures

Analytical procedures, including compendial and non-compendial methods, will be used to assess the strength, identity, purity and stability of mRNA-1273 LS Injection. Descriptions of the analytical procedures are provided in the following section. Please note that the analytical procedures applicable for both the mRNA-1273 LS Lipid Nanoparticle (LNP) and mRNA-1273 LS Injection are presented in [Section 3.2.S.4.2 {mRNA-1273 LNP}](#) as described in the following table.

Table 1: Analytical Procedure and Reference in Section 3.2.S.4.2

Analytical Procedure	Reference Section
Appearance	Section 3.2.S.4.2.1 {mRNA-1273 LNP}
Identity by Reverse Transcription/Sanger Sequencing	Section 3.2.S.4.2.2 {mRNA-1273 LNP}
RNA Content by AEX-HPLC	Section 3.2.S.4.2.3 {mRNA-1273 LNP}
Purity by RP-HPLC	Section 3.2.S.4.2.4 {mRNA-1273 LNP}
% RNA Encapsulation by Fluorescence (RiboGreen)	Section 3.2.S.4.2.5 {mRNA-1273 LNP}
Mean Particle Size and Polydispersity by Dynamic Light Scattering	Section 3.2.S.4.2.6 {mRNA-1273 LNP}
Lipid Identification by UPLC-CAD	Section 3.2.S.4.2.7 {mRNA-1273 LNP}
Lipid Content by UPLC-CAD	Section 3.2.S.4.2.8 {mRNA-1273 LNP}
Lipid Impurities by UPLC-CAD	Section 3.2.S.4.2.9 {mRNA-1273 LNP}
pH	Section 3.2.S.4.2.10 {mRNA-1273 LNP}
Osmolality	Section 3.2.S.4.2.11 {mRNA-1273 LNP}
Bacterial Endotoxin	Section 3.2.S.4.2.13 {mRNA-1273 LNP}

Analytical methods for the mRNA-1273 LS Injection are described in the following section.

(b) (4)

(b) (4)



3.2.P.5.2.3 Container Content

mRNA-1273 LS Injection container content is tested in accordance with USP <697>.

3.2.P.5.2.4 Sterility

mRNA-1273 LS Injection is tested for sterility in accordance with USP <71> and EP 2.6.1 using (b) (4) .