

3.2.S.4.2 Analytical Procedures

The analytical methods used for the release and stability testing of mRNA-1273 LNP lots are described in the sections indexed in [Table 1](#). All methods except Bioburden are the same as used for Drug Product, thus reference is made for those summaries to 3.2.P.5.2 sections as applicable.

Table 1: Index of Analytical Method Descriptions for mRNA-1273 LNP

Test	Method	Section
Appearance	Visual	Section 3.2.S.4.2 {mRNA-1273 LNP - Appearance} Section 3.2.P.5.2 {Appearance}
Identity	RTSS	Section 3.2.S.4.2 {mRNA-1273 LNP - Identity} Section 3.2.P.5.2 {Identity}
Total RNA Content	AEX-HPLC	Section 3.2.S.4.2 {mRNA-1273 LNP – Total RNA Content} Section 3.2.P.5.2 {Total RNA Content}
Purity Product-Related Impurities	RP-IP-HPLC	Section 3.2.S.4.2 {mRNA-1273 LNP – Purity and Product-Related Impurities} Section 3.2.S.4.2 {mRNA-1273 LNP – Purity and Product-Related Impurities – Direct Injection} Section 3.2.P.5.2 {Purity and Product-Related Impurities} Section 3.2.P.5.2 {Purity and Product-Related Impurities – Direct Injection}
%RNA Encapsulation	(b) (4)	Section 3.2.S.4.2 {mRNA-1273 LNP - % RNA Encapsulation} Section 3.2.P.5.2 {% RNA Encapsulation}
Filtered Mean Particle Size	DLS	Section 3.2.S.4.2 {mRNA-1273 LNP – Particle Size and Polydispersity} Section 3.2.P.5.2 {Particle Size and Polydispersity}
Filtered Polydispersity		
Lipid Identification	HPLC-CAD	Section 3.2.S.4.2 {mRNA-1273 LNP – Lipid Identification, Lipid Content, Lipid Impurities} Section 3.2.P.5.2 {mRNA-1273 LNP – Lipid Identification, Lipid Content, Lipid Impurities}
Lipid Content		
pH	USP <791>	Section 3.2.S.4.2 {mRNA-1273 LNP - pH} Section 3.2.P.5.2 {pH}
Osmolality – Freezing Point Depression	USP <785>	Section 3.2.S.4.2 {mRNA-1273 LNP - Osmolality} Section 3.2.P.5.2 {Osmolality}
Bacterial Endotoxins	USP <85>, Ph. Eur. 2.6.14	Section 3.2.S.4.2 {mRNA-1273 LNP – Bacterial Endotoxin} Section 3.2.P.5.2 {Bacterial Endotoxin}
Bioburden	USP <61>, Ph. Eur. 2.6.12	Section 3.2.S.4.2 {mRNA-1273 LNP - Bioburden}

Abbreviations: AEX-HPLC = anion exchange high-performance liquid chromatography; DLS = dynamic light scattering; (b) (4) RP-IP-HPLC = reverse-phase ion-paired high-performance liquid chromatography; RTSS = reverse transcription Sanger sequencing