

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

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