

3.2.S.4.3 Validation of Analytical Procedures

The analytical procedures for used for release and stability testing of mRNA-1273 LNP lots were confirmed as suitable for their intended use through method validation and/or qualification studies. Summaries of these studies are indexed in [Table 1](#). All methods except Bioburden are the same as used for Drug Product, thus reference is made for those summaries to Section 3.2.P.5.3.

Table 1: Index of Method Validation Summaries for mRNA-1273 LNP

Test	Method	Section
Appearance	Visual	Section 3.2.P.5.3 {Appearance}
Identity	RTSS	Section 3.2.P.5.3 {Identity}
Total RNA Content	AEX-HPLC	Section 3.2.P.5.3 {RNA Content}
Purity Product-Related Impurities	RP-IP-HPLC	Section 3.2.P.5.3 {Purity and Product-Related Impurities}
		Section 3.2.P.5.3 {Purity and Product-Related Impurities - Direct Injection}
%RNA Encapsulation	(b) (4)	Section 3.2.P.5.3 {% RNA Encapsulation}
Filtered Mean Particle Size	DLS	Section 3.2.P.5.3 {Particle Size and Polydispersity}
Filtered Polydispersity		
Lipid Identification	HPLC-CAD	Section 3.2.P.5.3 (Lipid ID, Lipid Content, Lipid Impurities)
Lipid Content		
pH	USP <791>	Section 3.2.P.5.3 {pH}
Osmolality – Freezing Point Depression	USP <785>	Section 3.2.P.5.3 {Osmolality}
Bacterial Endotoxins	USP <85>, Ph. Eur. 2.6.14	Section 3.2.P.5.3 {Bacterial Endotoxin}
Bioburden	USP <61>, Ph. Eur. 2.6.12	Section 3.2.S.4.3 {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-pair high-performance liquid chromatography; RPIP-HPLC = reverse-phase ion-paired high-performance liquid chromatography; RTSS = reverse transcription Sanger sequencing