

3.2.P.5.2 Analytical Procedures

The analytical methods used for the release and stability testing of mRNA-1273 DP lots are described in the sections indexed in [Table 1](#).

Table 1: Index of Method Summaries for Drug Product

Test	Method	Section
Appearance	Visual	Section 3.2.P.5.2 {Appearance}
Identity	RTSS	Section 3.2.P.5.2 {Identity}
Total RNA Content	AEX-HPLC	Section 3.2.P.5.2 {Total RNA Content}
Purity	RP-IP-HPLC	Section 3.2.P.5.2 {Purity and Product-related Impurities}
Product-Related Impurities		Section 3.2.P.5.2 {Purity and Product-related Impurities – Direct Injection}
%RNA Encapsulation	(b) (4)	Section 3.2.P.5.2 {%RNA Encapsulation}
Particle Size	DLS	Section 3.2.P.5.2 {Particle Size and Polydispersity}
Polydispersity		
Lipid Identification	HPLC-CAD	Section 3.2.P.5.2 {Lipid Identification, Lipid Content, Lipid Impurities}
Lipid Content (mg/mL)		
Lipid Impurities		
Particulate Matter	USP <788>, Method 2	Section 3.2.P.5.2 {Particulate Matter}
pH	USP <791>	Section 3.2.P.5.2 {pH}
Osmolality – Freezing Point Depression	USP <785>	Section 3.2.P.5.2 {Osmolality}
In Vitro Translation	SOP-0937	Section 3.2.P.5.2 {In Vitro Translation}
Container Content	SOP-1229 (based on USP <697>)	Section 3.2.P.5.2 {Container Content}
Bacterial Endotoxins	USP <85>, Ph. Eur. 2.6.14	Section 3.2.P.5.2 {Bacterial Endotoxins}
Sterility	USP <71>, Ph Eur. 2.6.1	Section 3.2.P.5.2 {Sterility}
Container Closure Integrity	(b) (4)	Section 3.2.P.5.2 {Container Closure Integrity}

Abbreviations: AEX-HPLC = anion exchange high-performance liquid chromatography; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; DLS = dynamic light scattering; (b) (4) (b) (4) RTSS = reverse transcription Sangar sequencing; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection