

3.2.S.4.1 Specification

Testing of mRNA-1273 LNP is performed in accordance with the specification listed in [Table 1](#).

Table 1: Specification for mRNA-1273 LNP

Test	Method	Method Number	Specification
Appearance	Visual	SOP-0278	(b) (4)
Identity	RTSS	SOP-1032	
Total RNA Content	AEX-HPLC	SOP-0999	
Purity Product-Related Impurities	RP-IP-HPLC	SOP-1142	
%RNA Encapsulation	(b) (4)	SOP-1000	
Filtered Mean Particle Size	Dynamic light scattering	SOP-0998	
Filtered Polydispersity			
Lipid Identification			
SM-102	HPLC-CAD	SOP-1001	
Cholesterol			
DSPC			
PEG2000-DMG			
Lipid Content			
SM-102	HPLC-CAD	SOP-1001	
Cholesterol			
DSPC			
PEG2000-DMG			
Lipid Impurity			
pH	USP <791>	SOP-0288	
Osmolality – Freezing Point Depression	USP <785>	SOP-0279	
Bacterial Endotoxins	USP <85>, Ph. Eur. 2.6.14	M-CTS-CS-0929	
Bioburden	USP <61>, Ph. Eur. 2.6.12	SOP-0480 GROUP-109208	

Abbreviations: AEX = anion exchange chromatography; CAD = charged aerosol detection; CFU = colony-forming unit(s); DP = drug product; EU = endotoxin unit(s); HPLC-CAD = high-performance liquid chromatography; IG = impurity group; (b) (4) RP = reverse phase; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; (b) (4) RT = reverse transcription; RTSS = reverse transcription Sanger sequencing; TAMC = total aerobic microbial count; TYMC = total combined yeasts and molds count