

3.2.P.5.1 Specifications

The specification for mRNA-1273 Drug Product is provided in [Table 1](#).

Table 1: Specification for Drug Product

Test	Method	Method Number	Acceptance Criteria
Appearance	Visual	SOP-0278	White to off-white dispersion. May contain visible, white or translucent product-related particulates
Identity	RTSS	SOP-1032	(b) (4)
Total RNA Content	AEX-HPLC	SOP-0999	
Purity Product-Related Impurities	RP-IP-HPLC	SOP-1142	
%RNA Encapsulation	(b) (4)	SOP-1000	
Particle Size	DLS	SOP-0998	
Polydispersity			
Lipid (b) (4)	HPLC-CAD	SOP-1001	
SM-102			
Cholesterol			
DSPC			
PEG2000-DMG			
Lipid Content (mg/mL)	HPLC-CAD	SOP-1001	
SM-102			
Cholesterol			
DSPC			
PEG2000-DMG			
Lipid Impurity			
Particulate Matter			
≥ 25µm particulate matter	USP <788>	SOP-0509	
≥ 10 µm particulate matter	Method 2		
pH	USP <791>	SOP-0288	
Osmolality – Freezing Point Depression	USP <785>	SOP-0279	
In Vitro Translation	Cell-Free In Vitro Translation and gel electrophoresis	SOP-0937	
Container Content	Based on USP <697>	SOP-1229 ^(a)	5.5 mL Presentation Syringe/Needle: Option A: 11 doses of 0.5 mL from 1 vial Option B: 10 doses of 0.5 mL from 1 vial
Bacterial Endotoxins	USP <85>, Ph. Eur. 2.6.14	M_CTS_CS_0929	(b) (4)
Sterility	USP <71>, Ph Eur. 2.6.1	A-SOP-09-07-015 and AM-MICRO-256-100-001 or 07-02-003	
Container Closure Integrity (stability only)	(b) (4)	803-TM 895-TM	

Abbreviations: AEX-HPLC = anion exchange high-performance liquid chromatography; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; DLS = dynamic light scattering; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; EU = endotoxin unit(s); (b) (4) (b) (4) RP-HPLC = reverse-phase high-performance liquid chromatography; (b) (4) RTSS = reverse transcription Sangar sequencing; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

(b) (4)