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)			
SM-102	HPLC-CAD	SOP-1001	
Cholesterol			
DSPC			
PEG2000-DMG			
Lipid Content (mg/mL)			
SM-102	HPLC-CAD	SOP-1001	
Cholesterol			
DSPC			
PEG2000-DMG			
Lipid Impurity			
Particulate Matter			
≥ 25µm particulate matter	USP <788> Method 2	SOP-0509	
≥ 10 µm particulate matter			
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 **7.5 mL Presentation** Syringe/Needle: Option A: 15 doses of 0.5 mL from 1 vial Option B: 13 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	**End of Shelf Life** Pass

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)

3.2.P.5.1.1 Release Test Sampling

Release testing is performed on either labeled or unlabeled filled vials as indicated in Table 2. In compliance with 21 CRF 610.14, the release samples for identity testing are selected after all labeling operations are completed and tested according to the method referenced in Table 1.

Table 2: Release Test Samples

Release Test	Release test Sample	
	Catalent	**Baxter**
Appearance	Labeled	Labeled
Identity	Labeled	Labeled
Total RNA Content	Labeled	Labeled
Purity Product-Related Impurities	Unlabeled [(a)]	Labeled
%RNA Encapsulation	Labeled	Labeled
Particle Size	Labeled	Labeled
Polydispersity	Labeled	Labeled
Lipid Identification	Labeled	Labeled
Lipid Content	Labeled	Labeled
Lipid Impurity	Labeled	Labeled
Particulate Matter	Unlabeled	Labeled
pH	Labeled	Labeled
Osmolality – Freezing Point Depression	Labeled	Labeled
In Vitro Translation	Labeled	Labeled
Container Content	Labeled	Labeled
Bacterial Endotoxins	Unlabeled	Labeled
Sterility	Unlabeled	Unlabeled

(A) (b) (4)