3.2.P.5.1 Specifications

The specification for mRNA-1273 Drug Product is provided in Table 1.

Table 1: mRNA-1273 Drug Product Specification

Test	Method	Acceptance Criteria
Appearance	Visual (SOP-0278)	White to off-white dispersion. May contain visible, white or translucent product-related particulates.
RNA content	Anion Exchange (AEX) HPLC (SOP-0999)	[redacted] (Target: [redacted])
Identity	Reverse Transcription/Sanger Sequencing (SOP-1032)	Sequence matches description
Purity	RP-HPLC (SOP-0996)	[redacted] main peak area [a]
Product-related impurities		Report % area for each impurity group: [redacted] (pre-main peak area) (post-main peak area) (mRNA-adduct species)
% RNA encapsulation	[redacted] (SOP-1000)	[redacted]
In Vitro Translation	In Vitro Translation/Methionine Labelling (SOP-0937)	(Target: [redacted])
Lipid identification		
SM-102	UPLC-CAD (SOP-1001)	Matches retention time of reference
Cholesterol		Matches retention time of reference
DSPC		Matches retention time of reference
PEG2000-DMG		Matches retention time of reference
Lipid content		
SM-102	UPLC-CAD (SOP-1001)	[redacted]
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid impurities	UPLC-CAD (SOP-1001)	Individual impurities: [redacted] area (report RRTs) Total impurities: [redacted] area
Particle size	Dynamic Light Scattering (SOP-0998)	[redacted]
Polydispersity		
pH	USP <791> (SOP-0288)	
Osmolality	USP <785> Freezing Point Depression (SOP-0279)	
Particulate matter		
≥ 25 µm	USP <788> Method 2 (SOP-0509)	[redacted] per container
≥ 10 µm		[redacted] per container
Container content	USP <697> (SOP-0950)	[redacted] from 1 vial)
Bacterial endotoxin	USP <85>, EP 2.6.14	[redacted]
Sterility	USP <71>, EP 2.6.1	No growth

a) Applies to release testing only. Stability acceptance criteria for %purity by RP-HPLC is [redacted] purity.
RRT = relative retention time