

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-0235)	(b) (4)
Identity	Reverse Transcription/ Sanger Sequencing (SOP-0544)	
Purity	RP-HPLC (SOP-0383)	
Product-related impurities		
% RNA encapsulation	(b) (4)	
In Vitro Translation (Potency)	In Vitro Translation (b) (4) (SOP-0937)	
Lipid identification		
SM-102	UPLC-CAD (SOP-0502)	(b) (4)
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid content		(b) (4)
SM-102	UPLC-CAD (SOP-0502)	
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid impurities	UPLC-CAD (SOP-0502)	
Particle size	Dynamic Light Scattering (SOP-0107)	
Polydispersity		
pH	USP <791> (SOP-0288)	
Osmolality	USP <785> Freezing Point Depression (SOP-0279)	
Particulate matter		(b) (4)
≥ 25 μm	USP <788> Method 2 (SOP-0509)	
≥ 10 μm		
Container content	USP <697> (SOP-0950)	≥ 5.0 mL (≥ 10 doses of 0.5 mL from 1 vial)
Bacterial endotoxin	USP <85>, EP 2.6.14 (M-CTS-CS-0929)	(b) (4)
Sterility	USP <71>, EP 2.6.1 (A-SOP-09-07-015)	

a = Applies to release testing only. Stability acceptance criteria for %purity by RP-HPLC is (b) (4)

(b) (4)