

3.2.P.5.1 Specifications

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

Table 1: mRNA-1273 LS Injection Specification

Test	Method	Specification
Appearance	Visual	White to off-white dispersion. May contain visible, white or translucent product-related particulates.
RNA content	Anion Exchange (AEX) HPLC	(b) (4)
Identity	Reverse Transcription/ Sanger Sequencing	
Purity	RP-HPLC	
Product-related impurities		
% RNA encapsulation		
In Vitro Translation (Potency)	In Vitro Translation	
Lipid identification		
SM-102	UPLC-CAD	
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid content		(b) (4)
SM-102	UPLC-CAD	
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid impurities	UPLC-CAD	
Particle size	Dynamic Light Scattering	
Polydispersity		
pH	USP <791>	
Osmolality	USP <785> Freezing Point Depression	
Particulate matter		(b) (4)
≥ 25 μm	USP <788> Method 2	
≥ 10 μm		
Container content	USP <697>	
Bacterial endotoxin	USP <85>, EP 2.6.14	
Sterility	USP <71>, EP 2.6.1	

a = Applies to release testing only. Stability specification for %purity by RP-HPLC is (b) (4)
RT = retention time

(b) (4)