

3.2.S.4.1 SPECIFICATION

The specification for mRNA-1273 Lipid Nanoparticle (LNP) is described in [Table 1](#).

Table 1: mRNA-1273 LNP Specification

Test	Analytical Method	Acceptance Criteria
Appearance	Visual (SOP-0278)	(b) (4)
Identity	Reverse Transcription/ Sanger Sequencing (SOP-1032)	
Total RNA content	Anion Exchange HPLC (SOP-0999)	
Purity	RP- HPLC (SOP-0996)	
Product-related impurities		
% RNA encapsulation	(b) (4) (SOP-1000)	
Mean particle size	Dynamic Light Scattering (SOP-0998)	
Polydispersity		
Lipid identification		
SM-102	UPLC-CAD (SOP-1001)	
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid content		
SM-102	UPLC-CAD (SOP-1001)	
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid impurities	UPLC-CAD (SOP-1001)	
pH	USP <791> (SOP-0288)	
Osmolality	USP <785> (SOP-0279)	
Bacterial endotoxin	USP <85>, EP 2.6.14 (M-CTS-CS-0929)	
Bioburden	USP <61>, EP 2.6.12 (SOP-0480)	

RT= retention time

(b) (4)