

3.2.P.5.4 Batch Analyses

Batch analysis data for mRNA-1273 Injection GMP Lot 6007520001, Lot 6007520002 and Lot 6007520003 was generated in accordance with the specification listed in [Table 1](#) (valid at the time of release). Batch analysis data for mRNA-1273 Injection GMP Lot 6007520004, Lot 6007520005, Lot 6007520006 and Lot 6007520007 was generated in accordance with the specification as provided in [Section 3.2.P.5.1](#). The certificates of analysis for GMP mRNA-1273 Injection lots in [Table 1](#) are provided as an attachment ([CofAs mRNA-1273 Drug Product Lots](#)).

Table 1: Batch Analysis Data for mRNA-1273 Injection

mRNA-1273 Injection GMP Lot Number		6007520001	6007520002	6007520003	6007520004	6007520005	6007520006	6007520007	
Date of Manufacture		28May2020	02Jun2020	04Jun2020	25Jun2020	30Jun2020	08Jul2020	09Jul2020	
Test	Specification	Result	Result	Result	Result	Result	Result	Result	
Appearance	White to off-white dispersion. May contain visible, white or translucent product-related particulates	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	
RNA content by AEX-HPLC	(b) (4)	0.21	0.20	0.22	0.19	0.20	0.20	0.20	
Identity by Rev Transcription/Sanger Sequencing		(b) (4)							
Purity by RP-HPLC		(b) (4)				N/A	N/A	N/A	N/A
Product-related impurities by RP-HPLC		N/A				(b) (4)			
		(b) (4)				(b) (4)			
% RNA encapsulation by Fluorescence (RiboGreen)									
In vitro Translation (Potency)									
pH									
Osmolality									
Particle size by Dynamic Light Scattering									
Polydispersity by Dynamic Light Scattering	(b) (4)	Report results				(b) (4)	N/A	N/A	N/A
		N/A	N/A	N/A	N/A	(b) (4)			
Lipid identification by UPLC-CAD									
SM-102		Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	
Cholesterol		Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	
DSPC		Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	
PEG2000-DMG		Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	
Lipid content by UPLC-CAD									
SM-102		(b) (4)				(b) (4)			
Cholesterol									
DSPC					N/A	N/A	N/A	N/A	
	N/A	N/A	N/A	(b) (4)					
PEG2000-DMG	(b) (4)								

mRNA-1273 Injection GMP Lot Number		6007520001	6007520002	6007520003	6007520004	6007520005	6007520006	6007520007
Date of Manufacture		28May2020	02Jun2020	04Jun2020	25Jun2020	30Jun2020	08Jul2020	09Jul2020
Test	Specification	Result	Result	Result	Result	Result	Result	Result
Lipid impurities by UPLC-CAD	(b) (4)	(b) (4)	(b) (4)					
Particulate matter	(b) (4)	(b) (4)						
≥ 25 µm								
≥ 10 µm								
Container content								
Bacterial endotoxin								
Sterility								

a) The release specification is (b) (4) for %purity. The stability specification for %purity is (b) (4) as presented in [Section 3.2.P.8.3](#)

N/A = specification is not applicable for product

kDa = kilodalton

RT = retention time

(b) (4)