

Table of Contents

Table of Contents ..... 1

List of Tables.....2

3.2.P.8.3   Stability Data .....4

3.2.P.8.3.1    Stability Data for Development mRNA-1273 LS Injection.....5

3.2.P.8.3.2    Stability Data for GMP mRNA-1273 LS Injection..... 11

3.2.P.8.3.3    Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection.....23

3.2.P.8.3.4    Clinical In-Use Compatibility Data for mRNA-1273 LS Injection .....27

### List of Tables

Table 1:	Stability Results for Development mRNA-1273 LS Injection, DHM-47519 (0.10 mg/mL) Stored Between -60°C to -90°C .....	5
Table 2:	Stability Results for Development mRNA-1273 LS Injection, DHM-47519 (0.10 mg/mL) Stored Between -15°C to -25°C .....	6
Table 3:	Stability Results for Development mRNA-1273 LS Injection, DHM-47519 (0.10 mg/mL) Stored Between 2°C to 8°C .....	7
Table 4:	Stability Results for Development mRNA-1273 LS Injection, DHM-47516 (0.5 mg/mL) Stored Between -60°C to -90°C .....	8
Table 5:	Stability Results for Development mRNA-1273 LS Injection, DHM-47516 (0.5 mg/mL) Stored Between -15°C to -25°C .....	9
Table 6:	Stability Results for Development mRNA-1273 LS Injection, DHM-47516 (0.5 mg/mL) Stored Between 2°C to 8°C .....	10
Table 7:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between -60°C to -90°C .....	11
Table 8:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between -15°C to -25°C .....	12
Table 9:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between 2°C to 8°C .....	13
Table 10:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between 23°C to 27°C .....	14
Table 11:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between -60°C to -90°C .....	15
Table 12:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between -15°C to -25°C .....	16
Table 13:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between 2°C to 8°C .....	17
Table 14:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between 23°C to 27°C .....	18
Table 15:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between -60°C to -90°C .....	19
Table 16:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between -15°C to -25°C .....	20
Table 17:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between 2°C to 8°C .....	21
Table 18:	Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between 23°C to 27°C .....	22
Table 19:	Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47522 (0.10 mg/mL) Stored Between -60°C to -90°C and Thawed to Room Temperature .....	23

Table 20:	Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47522 (0.10 mg/mL) Stored Between -60°C to -90°C and Thawed to 2°C to 8°C ....	24
Table 21:	Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47518 (0.5 mg/mL) Stored Between -60°C to -90°C and Thawed to Room Temperature .....	25
Table 22:	Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47518 (0.5 mg/mL) Stored Between -60°C to -90°C and Thawed to 2°C to 8°C .....	26
Table 23:	Clinical In-Use Compatibility Data for mRNA-1273 LS Injection, Lot 6006820001, 0.10 mg /mL, (b) (4) Unopened Multi-Dose Vial	27
Table 24:	Clinical In-Use Compatibility Data for mRNA-1273 LS Injection, Lot 6006820001, 0.10 mg /mL, (b) (4) Post 6 Hour Hold of Opened Multi-Dose Vial.....	28
Table 25:	Clinical In-Use Compatibility Data for mRNA-1273 LS Injection, Lot 6006820001, 0.10 mg /mL, (b) (4) Post 6 Hour Hold of Opened Multi-Dose Vial.....	29
Table 26:	Clinical In-Use Compatibility Data for mRNA-1273 LS Injection Lot 6006920001, 0.5 mg /mL, (b) (4) Unopened Multi-Dose Vial ..	30
Table 27:	Clinical In-Use Compatibility Data for mRNA-1273 LS Injection, Lot 6006920001, 0.5 mg /mL, (b) (4) Post 6 Hour Hold of Opened Multi-Dose Vial.....	31
Table 28:	Clinical In-Use Compatibility Data for mRNA-1273 LS Injection, Lot 6006920001, 0.5 mg /mL, (b) (4) Post 6 Hour Hold of Opened Multi-Dose Vial.....	32

### 3.2.P.8.3 Stability Data

Stability data for the development mRNA-1273 LS Injection, Lot DHM-47519 (0.10 mg/mL) are provided in [Table 1](#) to [Table 3](#).

Stability data for the development mRNA-1273 LS Injection, Lot DHM-47516 (0.5 mg/mL) are provided in [Table 4](#) to [Table 6](#).

Stability data for the GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) are provided in [Table 7](#) to [Table 10](#).

Stability data for the GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) are provided in [Table 11](#) to [Table 14](#).

Stability data for the GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) are provided in [Table 15](#) to [Table 18](#).

Freeze-thaw cycling stability data for the mRNA-1273 LS Injection Lot DHM-47522 (0.10 mg/mL) are provided in [Table 19](#) to [Table 20](#).

Freeze-thaw cycling stability data for the mRNA-1273 LS Injection Lot DHM-47518 (0.5 mg/mL) are provided in [Table 21](#) to [Table 22](#).

The clinical in-use stability results for mRNA-1273 LS Injection, Lot 6006820001 (0.10 mg/mL) is provided in [Table 23](#) to [Table 25](#).

The clinical in-use stability results for mRNA-1273 LS Injection, Lot 6006920001 (0.5 mg/mL) is provided in [Table 26](#) to [Table 28](#).

### 3.2.P.8.3.1 Stability Data for Development mRNA-1273 LS Injection

**Table 1: Stability Results for Development mRNA-1273 LS Injection, DHM-47519 (0.10 mg/mL) Stored Between -60°C to -90°C**

Test	Specification	0	1 month	3 month	6 month	9 month	12 month	18 month	24 month	36 month	48 month
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							
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A							
RNA content by AEX-HPLC	(b) (4)										
Purity by RP-HPLC											
Product-related impurities by RP-HPLC											
% RNA encapsulation by (b) (4)											
Lipid identification by UPLC-CAD											
SM102	(b) (4)	(b) (4)	N/A	(b) (4)							
Cholesterol			N/A								
DSPC			N/A								
PEG2000-DMG			N/A								
Lipid content by UPLC-CAD											
SM102	(b) (4)		N/A	(b) (4)							
Cholesterol			N/A								
DSPC			N/A								
PEG2000-DMG			N/A								
Lipid impurities by UPLC-CAD			N/A								
Mean particle size by Dynamic light scattering	(b) (4)										
Polydispersity by Dynamic light scattering	Report result	(b) (4)									
pH	(b) (4)		N/A	(b) (4)							
In Vitro Translation (Potency)			N/A								
Osmolality			N/A	N/A							
Particulate matter			N/A	N/A							
Bacterial endotoxin			N/A	N/A							
Bioburden			N/A	N/A							

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

\*Sample handling issue with %purity samples. An additional sample was pulled at 50 days on 21Mar20 for %purity by RP-HPLC analysis. The data were used for 1M results.

**Table 2: Stability Results for Development mRNA-1273 LS Injection, DHM-47519 (0.10 mg/mL) Stored Between -15°C to -25°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	2 month	3 month	6 month	9 month	12 month	24 month	48 month
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					
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A					
RNA content by AEX-HPLC	(b) (4)								
Purity by RP-HPLC									
Product-related impurities by RP-HPLC									
% RNA encapsulation by (b) (4)									
Lipid identification by UPLC-CAD									
SM102	(b) (4)	(b) (4)	N/A	(b) (4)					
Cholesterol			N/A						
DSPC			N/A						
PEG2000-DMG			N/A						
Lipid content by UPLC-CAD									
SM102	(b) (4)		N/A	(b) (4)					
Cholesterol			N/A						
DSPC			N/A						
PEG2000-DMG			N/A						
Lipid impurities by UPLC-CAD			N/A						
Mean particle size by Dynamic light scattering	(b) (4)	(b) (4)							
Polydispersity by Dynamic light scattering	Report result								
pH	(b) (4)		N/A						
In Vitro Translation (Potency)			N/A	141					
Osmolality			N/A	N/A					
Particulate matter			N/A	N/A					
Bacterial endotoxin			N/A	N/A					
Bioburden			N/A	N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

**Table 3: Stability Results for Development mRNA-1273 LS Injection, DHM-47519 (0.10 mg/mL) Stored Between 2°C to 8°C**

Test	Specification	0	1 month	2 month	3 month	4 month	5 month
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		
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A	N/A		
RNA content by AEX-HPLC	(b) (4)						
Purity by RP-HPLC							
Product related impurities by RP-HPLC							
% RNA encapsulation by (b) (4)							
Lipid identification by UPLC-CAD							
SM102	(b) (4)	(b) (4)	N/A	(b) (4)			
Cholesterol			N/A				
DSPC			N/A				
PEG2000-DMG			N/A				
Lipid content by UPLC-CAD							
SM102	(b) (4)		N/A	(b) (4)			
Cholesterol			N/A				
DSPC			N/A				
PEG2000-DMG			N/A				
Lipid impurities by UPLC-CAD			N/A				
Mean particle size by Dynamic light scattering	(b) (4)	(b) (4)					
Polydispersity by Dynamic light scattering	Report result						
pH	(b) (4)		N/A	(b) (4)			
In Vitro Translation (Potency)			N/A				
Osmolality			N/A				
Particulate matter			N/A				
Bacterial endotoxin			N/A				
Bioburden			N/A				

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4) \*Sample handling issue with %purity samples.  
An additional sample was pulled at 50 days on 21Mar20 for %purity by RP-HPLC analysis. The data were used for 1M results.

**Table 4: Stability Results for Development mRNA-1273 LS Injection, DHM-47516 (0.5 mg/mL) Stored Between -60°C to -90°C**

Test	Specification	0	1 month	3 month	6 month	9 month	12 month	18 month	24 month	36 month	48 month	
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								
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A								
RNA content by AEX-HPLC	(b) (4)											
Purity by RP-HPLC												
Product related impurities by RP-HPLC												
% RNA encapsulation by (b) (4)												
Lipid identification by UPLC-CAD												
SM102	(b) (4)	(b) (4)	N/A	(b) (4)								
Cholesterol			N/A									
DSPC			N/A									
PEG2000-DMG			N/A									
Lipid content by UPLC-CAD												
SM102	(b) (4)		N/A	(b) (4)								
Cholesterol			N/A									
DSPC			N/A									
PEG2000-DMG			N/A									
Lipid impurities by UPLC-CAD			N/A									
	(b) (4)											
Mean particle size by Dynamic light scattering	(b) (4)	(b) (4)										
Polydispersity by Dynamic light scattering	Report result											
pH	(b) (4)		N/A									
In Vitro Translation (Potency)			N/A									
Osmolality			N/A	N/A								
Particulate matter			N/A	N/A								
Bacterial endotoxin			N/A	N/A								
Bioburden			N/A	N/A								

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

\*Sample handling issue with %purity samples. An additional sample was pulled at 50 days on 21Mar20 for % purity by RP-HPLC analysis. The data were used for 1M results.



**Table 5: Stability Results for Development mRNA-1273 LS Injection, DHM-47516 (0.5 mg/mL) Stored Between -15°C to -25°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	2 month	3 month	6month	9 month	12 month	24 month	48 month
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					
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A					
RNA content by AEX-HPLC	(b) (4)								
Purity by RP-HPLC									
Product-related impurities by RP-HPLC									
% RNA encapsulation by (b) (4)									
Lipid identification by UPLC-CAD									
SM102	(b) (4)	(b) (4)	N/A	(b) (4)					
Cholesterol			N/A						
DSPC			N/A						
PEG2000-DMG			N/A						
Lipid content by UPLC-CAD									
SM102	(b) (4)		N/A	(b) (4)					
Cholesterol			N/A						
DSPC			N/A						
PEG2000-DMG			N/A						
Lipid impurities by UPLC-CAD			N/A						
	(b) (4)								
Mean particle size by Dynamic light scattering	(b) (4)	(b) (4)							
Polydispersity by Dynamic light scattering	Report result								
pH	(b) (4)		N/A						
In Vitro Translation (Potency)			N/A						
Osmolality			N/A	N/A					
Particulate matter			N/A	N/A					
Bacterial endotoxin			N/A	N/A					
Bioburden			N/A	N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

**Table 6: Stability Results for Development mRNA-1273 LS Injection, DHM-47516 (0.5 mg/mL) Stored Between 2°C to 8°C**

Test	Specification	0	1 month	2 month	3 month	4 month	5 month
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		
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A	N/A		
RNA content by AEX-HPLC	(b) (4)						
Purity by RP-HPLC							
Product related impurities by RP-HPLC							
% RNA encapsulation by (b) (4)							
Lipid identification by UPLC-CAD							
SM102	(b) (4)	(b) (4)	N/A	(b) (4)			
Cholesterol			N/A				
DSPC			N/A				
PEG2000-DMG			N/A				
Lipid content by UPLC-CAD							
SM102	(b) (4)		N/A	(b) (4)	(b) (4)		
Cholesterol			N/A				
DSPC			N/A				
PEG2000-DMG			N/A				
Lipid impurities by UPLC-CAD			N/A				
	(b) (4)			(b) (4)			
Mean particle size by Dynamic light scattering	(b) (4)	(b) (4)					
Polydispersity by Dynamic light scattering	Report result						
pH	(b) (4)		N/A				
In Vitro Translation (Potency)			N/A				
Osmolality			N/A	N/A	N/A		
Particulate matter			N/A	N/A	N/A		
Bacterial endotoxin			N/A	N/A	N/A		
Bioburden			N/A	N/A	N/A		

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

\*Sample handling issue with %purity samples. An additional sample was pulled at 50 days on 21Mar20 for % purity by RP-HPLC analysis. The data were used for 1M results.

### 3.2.P.8.3.2 Stability Data for GMP mRNA-1273 LS Injection

**Table 7: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between -60°C to -90°C**

Test	Specification	0	1 month	2 month	3 month	6 month	9 month	12 month	18 month	24 month
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							
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A							
RNA content by AEX-HPLC	(b) (4)									
Purity by RP-HPLC										
Product related impurities by RP-HPLC										
% RNA encapsulation by (b) (4)										
Lipid identification by UPLC-CAD										
SM102	(b) (4)	(b) (4)								
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)							
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD										
Mean particle size by DLS			(b) (4)							
Polydispersity by DLS										
pH										
Osmolality			N/A							
In Vitro Translation (Potency)			(b) (4)							
Particulate matter			N/A							
Container content			N/A							
Bacterial endotoxin			N/A							
Sterility			N/A							

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 8: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between -15°C to -25°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	1 month	2 month	3 month	6 month	9 month	12 month
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					
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)								
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)					
Polydispersity by DLS								
pH								
Osmolality			N/A					
In Vitro Translation (Potency)			(b) (4)					
Particulate matter			N/A					
Container content			N/A					
Bacterial endotoxin			N/A					
Sterility			N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 9: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between 2°C to 8°C**

Test	Specification	0	1 month	2 month	76 days	3 month	4 month	6 month
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					
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)								
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)					
Polydispersity by DLS								
pH								
Osmolality			N/A					
In Vitro Translation (Potency)			(b) (4)					
Particulate matter			N/A					
Container content			N/A					
Bacterial endotoxin			N/A					
Sterility			N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4) = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 10: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520001 (0.20 mg/mL) Stored Between 23°C to 27°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	24 hours	72 hours
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
RNA content by AEX-HPLC	(b) (4)			
Purity by RP-HPLC				
Product related impurities by RP-HPLC				
% RNA encapsulation by (b) (4)				
Lipid identification by UPLC-CAD	(b) (4)			
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid content by UPLC-CAD	(b) (4)			
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid impurities by UPLC-CAD	(b) (4)			
Mean particle size by DLS	(b) (4)			
Polydispersity by DLS				
pH				
In Vitro Translation (Potency)				

kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 11: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between -60°C to -90°C**

Test	Specification	0	1 month	2 month	3 month	6 month	9 month	12 month	18 month	24 month
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							
RNA content by AEX-HPLC	(b) (4)									
Purity by RP-HPLC										
Product related impurities by RP-HPLC										
% RNA encapsulation by (b) (4)										
Lipid identification by UPLC-CAD										
SM102	(b) (4)	(b) (4)								
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)							
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD										
Mean particle size by DLS			(b) (4)							
Polydispersity by DLS										
pH										
Osmolality			N/A							
In Vitro Translation (Potency)			(b) (4)							
Particulate matter			N/A							
Container content			N/A							
Bacterial endotoxin			N/A							
Sterility			N/A							

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 12: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between -15°C to -25°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	1 month	2 month	3 month	6 month	9 month	12 month
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					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)								
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)					
Polydispersity by DLS								
pH								
Osmolality			N/A					
In Vitro Translation (Potency)			(b) (4)					
Particulate matter			N/A					
Container content			N/A					
Bacterial endotoxin			N/A					
Sterility			N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)



**Table 13: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between 2°C to 8°C**

Test	Specification	0	1 month	2 month	76 days	3 month	4 month	6 month
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					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)								
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS Polydispersity by DLS pH Osmolality In Vitro Translation (Potency)  Particulate matter Container content Bacterial endotoxin Sterility	(b) (4)							

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4) = (b) (4)  
a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 14: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520002 (0.20 mg/mL) Stored Between 23°C to 27°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	24 hours	72 hours
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
RNA content by AEX-HPLC	(b) (4)			
Purity by RP-HPLC				
Product related impurities by RP-HPLC				
% RNA encapsulation by (b) (4)				
Lipid identification by UPLC-CAD				
SM102	(b) (4)	(b) (4)		
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid content by UPLC-CAD				
SM102	(b) (4)		(b) (4)	
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid impurities by UPLC-CAD				
Mean particle size by DLS			(b) (4)	
Polydispersity by DLS				
pH				
In Vitro Translation (Potency)				

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 15: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between -60°C to -90°C**

Test	Specification	0	1 month	2 month	3 month	6 month	9 month	12 month	18 month	24 month
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							
RNA content by AEX-HPLC	(b) (4)									
Purity by RP-HPLC										
Product related impurities by RP-HPLC										
% RNA encapsulation by (b) (4)										
Lipid identification by UPLC-CAD										
SM102	(b) (4)		(b) (4)							
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)							
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD										
Mean particle size by DLS			(b) (4)							
Polydispersity by DLS										
pH										
Osmolality			N/A							
In Vitro Translation (Potency)			(b) (4)							
Particulate matter			N/A							
Container content			N/A							
Bacterial endotoxin			N/A							
Sterility			N/A							

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 16: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between -15°C to -25°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	1 month	2 month	3 month	6 month	9 month	12 month
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					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)								
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)					
Polydispersity by DLS								
pH								
Osmolality			N/A					
In Vitro Translation (Potency)			(b) (4)					
Particulate matter			N/A					
Container content			N/A					
Bacterial endotoxin			N/A					
Sterility			N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 17: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between 2°C to 8°C**

Test	Specification	0	1 month	2 month	76 days	3 month	4 month	6 month
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					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)								
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)					
Polydispersity by DLS								
pH								
Osmolality			N/A					
In Vitro Translation (Potency)			(b) (4)					
Particulate matter			N/A					
Container content			N/A					
Bacterial endotoxin			N/A					
Sterility			N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; (b) (4) = (b) (4)  
a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

**Table 18: Stability Results for GMP mRNA-1273 LS Injection, Lot 6007520003 (0.20 mg/mL) Stored Between 23°C to 27°C**

Test	Reference Criteria (Intended Storage at -60°C to -90°C)	0	24 hours	72 hours
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
RNA content by AEX-HPLC	(b) (4)	(b) (4)		
Purity by RP-HPLC				
Product related impurities by RP-HPLC				
% RNA encapsulation by (b) (4)				
Lipid identification by UPLC-CAD				
SM102	(b) (4)	(b) (4)	(b) (4)	
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid content by UPLC-CAD			(b) (4)	
SM102	(b) (4)			
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid impurities by UPLC-CAD			(b) (4)	
Mean particle size by DLS			(b) (4)	
Polydispersity by DLS				
pH				
In Vitro Translation (Potency)				

kDa = kilodalton; RT = retention time; (b) (4)

a = Applies to stability testing only. Release specification for purity by RP-HPLC is (b) (4)

### 3.2.P.8.3.3 Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection

**Table 19: Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47522 (0.10 mg/mL)  
Stored Between -60°C to -90°C and Thawed to Room Temperature**

Test	Target Criteria	Initial	Cycle A	Cycle B	Cycle C
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
% RNA encapsulation by (b) (4)	(b) (4)				
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering					

**Table 20: Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47522 (0.10 mg/mL)  
Stored Between -60°C to -90°C and Thawed to 2°C to 8°C**

Test	Target Criteria	Initial	Cycle A	Cycle B	Cycle C
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
% RNA encapsulation by (b) (4)	(b) (4)				
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering					



**Table 21: Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47518 (0.5 mg/mL)  
Stored Between -60°C to -90°C and Thawed to Room Temperature**

Test	Target Criteria	Initial	Cycle A	Cycle B	Cycle C
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
% RNA encapsulation by (b) (4)	(b) (4)				
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering					

**Table 22: Freeze/ Thaw Cycling Data for mRNA-1273 LS Injection, Lot DHM-47518 (0.5 mg/mL)  
Stored Between -60°C to -90°C and Thawed to 2°C to 8°C**

Test	Target Criteria	Initial	Cycle A	Cycle B	Cycle C
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
% RNA encapsulation by (b) (4)	(b) (4)				
Purity by RP-HPLC					
Product related impurities by RP-HPLC					
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering					

### 3.2.P.8.3.4 Clinical In-Use Compatibility Data for mRNA-1273 LS Injection

**Table 23: Clinical In-Use Compatibility Data for mRNA-1273 LS Injection, Lot 6006820001, 0.10 mg /mL, (b) (4) Unopened Multi-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5C	RT	5C
Appearance	Report result		White to off-white dispersion, essentially free of particulates				
RNA content by AEX-HPLC	(b) (4)						
Purity by RP-HPLC							
Product related impurities by RP-HPLC							
In Vitro Translation (Potency)							
% RNA encapsulation by (b) (4)							
Mean particle size by Dynamic light scattering	(b) (4)						
Polydispersity by Dynamic light scattering							
Lipid content by UPLC-CAD	(b) (4)						
SM-102							
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)							
pH	(b) (4)			N/A			
Osmolality				N/A			

\* Initial (T = 0) results were from samples drawn up into a polycarbonate syringe and immediately pooled in a sample collection vial.

The impact of syringe material is expected to be negligible in the short timeframe involved.

ND = not detected

N/A = not required per the stability protocol

(b) (4)

**Table 24: Clinical In-Use Compatibility Data for mRNA-1273 LS Injection,  
Lot 6006820001, 0.10 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multi-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h			
	Initial	T8h and T24h		RT	5C	RT	5C		
Appearance	Report result		White to off-white dispersion, essentially free of particulates						
RNA content by AEX-HPLC	(b) (4)								
Purity by RP-HPLC									
Product related impurities by RP-HPLC									
In Vitro Translation (Potency)									
% RNA encapsulation by (b) (4)									
Mean particle size by Dynamic light scattering	(b) (4)								
Polydispersity by Dynamic light scattering									
Lipid content by UPLC-CAD									
SM-102									
Cholesterol									
DSPC	(b) (4)								
PEG2000-DMG									
Lipid impurities by UPLC-CAD (Report RRT and % Area)									
pH						(b) (4)		N/A	
Osmolality								N/A	

\* Initial (T = 0) results were from samples drawn up into a polycarbonate syringe and immediately pooled in a sample collection vial.

The impact of syringe material is expected to be negligible in the short timeframe involved.

Values reported in **bold**, denote a value below acceptance criteria

ND = not detected

N/A = not required per the stability protocol

(b) (4)

**Table 25: Clinical In-Use Compatibility Data for mRNA-1273 LS Injection,  
Lot 6006820001, 0.10 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multi-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h		
	Initial	T8h and T24h		RT	5C	RT	5C	
Appearance	Report result		White to off-white dispersion, essentially free of particulates					
RNA content by AEX-HPLC	(b) (4)							
Purity by RP-HPLC								
Product related impurities by RP-HPLC								
In Vitro Translation (Potency)								
% RNA encapsulation by (b) (4)								
Mean particle size by Dynamic light scattering								
Polydispersity by Dynamic light scattering	Report result		(b) (4)					
Lipid content by UPLC-CAD								
SM-102	(b) (4)							
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD (Report RRT and % Area)								
pH	(b) (4)		N/A					
Osmolality			N/A					

\* Initial (T = 0) results were from samples drawn up into a polycarbonate syringe and immediately pooled in a sample collection vial.

The impact of syringe material is expected to be negligible in the short timeframe involved.

ND = not detected

N/A = not required per the stability protocol

(b) (4)

**Table 26: Clinical In-Use Compatibility Data for mRNA-1273 LS Injection**  
**Lot 6006920001, 0.5 mg /mL, (b) (4)**  
**Unopened Multi-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5C	RT	5C
Appearance	Report result		White to off-white dispersion, essentially free of particulates				
RNA content by AEX-HPLC	(b) (4)						
Purity by RP-HPLC							
Product related impurities by RP-HPLC							
In Vitro Translation (Potency)							
% RNA encapsulation by (b) (4)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result		(b) (4)				
Lipid content by UPLC-CAD							
SM-102	(b) (4)						
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)							
pH	(b) (4)			N/A			
Osmolality				N/A			

\* Initial (T = 0) results were from samples drawn up into a polycarbonate syringe and immediately pooled in a sample collection vial.

The impact of syringe material is expected to be negligible in the short timeframe involved.

ND = not detected

N/A = not required per the stability protocol

(b) (4)

**Table 27: Clinical In-Use Compatibility Data for mRNA-1273 LS Injection,  
Lot 6006920001, 0.5 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multi-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5C	RT	5C
Appearance	Report result		White to off-white dispersion, essentially free of particulates				
RNA content by AEX-HPLC	(b) (4)						
Purity by RP-HPLC							
Product related impurities by RP-HPLC							
In Vitro Translation (Potency)							
% RNA encapsulation by (b) (4)							
Mean particle size by Dynamic light scattering	(b) (4)						
Polydispersity by Dynamic light scattering							
Lipid content by UPLC-CAD	(b) (4)						
SM-102							
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)							
pH	(b) (4)			N/A			
Osmolality				N/A			

\* Initial (T = 0) results were from samples drawn up into a polycarbonate syringe and immediately pooled in a sample collection vial.

The impact of syringe material is expected to be negligible in the short timeframe involved.

ND = not detected

N/A = not required per the stability protocol

(b) (4)

**Table 28: Clinical In-Use Compatibility Data for mRNA-1273 LS Injection,  
Lot 6006920001, 0.5 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multi-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5C	RT	5C
Appearance	Report result		White to off-white dispersion, essentially free of particulates				
RNA content by AEX-HPLC	(b) (4)						
Purity by RP-HPLC							
Product related impurities by RP-HPLC							
In Vitro Translation (Potency)							
% RNA encapsulation by (b) (4)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering							
Lipid content by UPLC-CAD							
SM-102							
Cholesterol							
DSPC	(b) (4)						
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)							
pH							
Osmolality							
	(b) (4)				N/A		
					N/A		

\* Initial (T = 0) results were from samples drawn up into a polycarbonate syringe and immediately pooled in a sample collection vial.

The impact of syringe material is expected to be negligible in the short timeframe involved.

ND = not detected

N/A = not required per the stability protocol

(b) (4)