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### 3.2.P.8.3 Stability Data

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

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

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

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

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

Stability data for the GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) are provided in [Table 19](#) to [Table 22](#).

Stability data for the GMP mRNA-1273 Drug Product, Lot 6007520005 (0.20 mg/mL) are provided in [Table 23](#) to [Table 24](#).

Stability data for the GMP mRNA-1273 Drug Product, Lot 6007520006 (0.20 mg/mL) are provided in [Table 25](#) to [Table 26](#).

Freeze-thaw cycling stability data for the mRNA-1273 Drug Product Lot DHM-47522 (0.10 mg/mL) are provided in [Table 27](#) to [Table 28](#).

Freeze-thaw cycling stability data for the mRNA-1273 Drug Product Lot DHM-47518 (0.5 mg/mL) are provided in [Table 29](#) to [Table 30](#).

The clinical in-use stability results for mRNA-1273 Drug Product, Lot 6006820001 (0.10 mg/mL) is provided in [Table 31](#) to [Table 33](#).

The clinical in-use stability results for mRNA-1273 Drug Product, Lot 6006920001 (0.5 mg/mL) is provided in [Table 34](#) to [Table 36](#).

The clinical in-use stability results for mRNA-1273 Drug Product, Lot 6007520007 (0.20 mg/mL) is provided in [Table 37](#) to [Table 39](#).

### 3.2.P.8.3.1 Stability Data for Development mRNA-1273 Drug Product

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

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	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)	N/A						
Cholesterol											
DSPC											
PEG2000-DMG											
Lipid content by UPLC-CAD											
SM102	(b) (4)		N/A	(b) (4)	N/A						
Cholesterol											
DSPC											
PEG2000-DMG											
Lipid impurities by UPLC-CAD	(b) (4)		N/A	(b) (4)	N/A						
Mean particle size by Dynamic light scattering	(b) (4)										
Polydispersity by Dynamic light scattering	Report result	(b) (4)	(b) (4)								
pH	(b) (4)		N/A	(b) (4)	N/A						
In Vitro Translation			N/A								
Osmolality			N/A		N/A	N/A					
Particulate matter			N/A		N/A	N/A					
Bacterial endotoxin	(b) (4)		N/A	N/A	N/A						
Bioburden			N/A	N/A	N/A						

N/A = not required per the stability protocol; B, M, E = beginning, middle, end; 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 Drug Product, DHM-47519 (0.10 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition)**

Test	Acceptance Criteria	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	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	(b) (4)			(b) (4)	(b) (4)				
SM102									
Cholesterol									
DSPC									
PEG2000-DMG									
Lipid impurities by UPLC-CAD	(b) (4)		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			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;

B, M, E = beginning, middle, end; kDa = kilodalton; RT = retention time;

(b) (4)

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

Test	Acceptance Criteria	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	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	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	(b) (4)						
SM102	(b) (4)		N/A	(b) (4)		N/A	N/A
Cholesterol			N/A			N/A	
DSPC			N/A			N/A	
PEG2000-DMG			N/A			N/A	
Lipid content by UPLC-CAD	(b) (4)						
SM102	(b) (4)		N/A	(b) (4)		N/A	N/A
Cholesterol			N/A			N/A	
DSPC			N/A			N/A	
PEG2000-DMG			N/A			N/A	
Lipid impurities by UPLC-CAD	(b) (4)		N/A	(b) (4)		N/A	N/A
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering							
pH							
In Vitro Translation							
Osmolality	Report result	(b) (4)	(b) (4)				
Particulate matter	(b) (4)		N/A	(b) (4)		N/A	N/A
Bacterial endotoxin			N/A			N/A	
Bioburden			N/A			N/A	
			N/A			N/A	
			N/A			N/A	

N/A = not required per the stability protocol;

B, M, E = beginning, middle, end; 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 Drug Product, DHM-47516 (0.5 mg/mL) Stored Between -60°C to -90°C**

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	White to off-white dispersion, essentially free of particulates						
Identification by RT/ Sanger Sequencing	(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)		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)	(b) (4)									
Mean particle size by Dynamic light scattering											
Polydispersity by Dynamic light scattering	Report result										
pH	(b) (4)		N/A								
In Vitro Translation			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;

B, M, E = beginning, middle, end; 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 Drug Product, DHM-47516 (0.5 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition)**

Test	Acceptance Criteria	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	White to off-white dispersion, essentially free of particulates				
Identification by RT/ Sanger Sequencing	(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)		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	(b) (4)		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			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;

B, M, E = beginning, middle, end; kDa = kilodalton; RT = retention time; (b) (4)

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

Test	Acceptance Criteria	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	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)		N/A	N/A	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)		N/A	(b) (4)		N/A	N/A
Cholesterol			N/A			N/A	N/A
DSPC			N/A			N/A	N/A
PEG2000-DMG			N/A			N/A	N/A
Lipid content by UPLC-CAD							
SM102	(b) (4)		N/A	(b) (4)		N/A	N/A
Cholesterol			N/A			N/A	N/A
DSPC			N/A			N/A	N/A
PEG2000-DMG			N/A			N/A	N/A
Lipid impurities by UPLC-CAD			N/A			N/A	N/A
	(b) (4)						
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)		N/A	N/A
In Vitro Translation			N/A			N/A	N/A
Osmolality			N/A	N/A	N/A	N/A	N/A
Particulate matter			N/A	N/A	N/A	N/A	N/A
Bacterial endotoxin			N/A	N/A	N/A	N/A	N/A
Bioburden			N/A	N/A	N/A	N/A	N/A

N/A = not required per the stability protocol;

B, M, E = beginning, middle, end; 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.

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### 3.2.P.8.3.2 Stability Data for GMP mRNA-1273 Drug Product

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

Test	Reference Criteria Intended Storage -15°C to -25°C	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	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)		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)									
Cholesterol			N/A	N/A	N/A					
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)		(b) (4)					
Cholesterol				N/A						
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD										
Mean particle size by DLS			(b) (4)	(b) (4)	(b) (4)					
Polydispersity by DLS										
pH				N/A						
Osmolality			N/A	N/A	N/A					
In Vitro Translation			(b) (4)	N/A	(b) (4)					
Particulate matter			N/A	N/A	N/A					
Container content			N/A	N/A	N/A					
Bacterial endotoxin			N/A	N/A	N/A					
Sterility			N/A	N/A	N/A					

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

**Table 8: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520001 (0.20 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition)**

Test	Acceptance Criteria	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	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)		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)							
Cholesterol			N/A	N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)		(b) (4)			
Cholesterol				N/A				
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
			(b) (4)		(b) (4)			
Mean particle size by DLS				(b) (4)				
Polydispersity by DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation			(b) (4)	N/A	(b) (4)			
Particulate matter			N/A	N/A	N/A			
Container content			N/A	N/A	N/A			
Bacterial endotoxin			N/A	N/A	N/A			
Sterility			N/A	N/A	N/A			

N/A = not required per the stability protocol;

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

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

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

Test	Acceptance Criteria	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	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)		N/A	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)							
Cholesterol			N/A	N/A	N/A	N/A		
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)			(b) (4)		
Cholesterol				N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
			(b) (4)					
Mean particle size by DLS				(b) (4)				
Polydispersity by DLS								
pH				N/A	N/A			
Osmolality			N/A	N/A	N/A	N/A		
In Vitro Translation			(b) (4)	N/A	N/A	(b) (4)		
Particulate matter			N/A	N/A	N/A	N/A		
Container content			N/A	N/A	N/A	N/A		
Bacterial endotoxin			N/A	N/A	N/A	N/A		
Sterility			N/A	N/A	N/A	N/A		

N/A = not required per the stability protocol;

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

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

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

[illegible]

kDa = kilodalton; RT = retention time; (b) (4)  
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is (b) (4)

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

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	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)		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)									
Cholesterol			N/A	N/A	N/A					
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)		(b) (4)					
Cholesterol				N/A						
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD										
			(b) (4)		(b) (4)					
Mean particle size by DLS				(b) (4)						
Polydispersity by DLS										
pH				N/A						
Osmolality			N/A	N/A	N/A					
In Vitro Translation			(b) (4)	N/A	(b) (4)					
Particulate matter			N/A	N/A	N/A					
Container content			N/A	N/A	N/A					
Bacterial endotoxin			N/A	N/A	N/A					
Sterility			N/A	N/A	N/A					

N/A = not required per the stability protocol;

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

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

**Table 12: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520002 (0.20 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition)**

Test	Acceptance Criteria	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	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)		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)							
Cholesterol			N/A	N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)		(b) (4)			
Cholesterol				N/A				
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)	(b) (4)	(b) (4)			
Polydispersity by DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation			(b) (4)	N/A	(b) (4)			
Particulate matter			N/A	N/A	N/A			
Container content			N/A	N/A	N/A			
Bacterial endotoxin			N/A	N/A	N/A			
Sterility			N/A	N/A	N/A			

N/A = not required per the stability protocol;

kDa = kilodalton;

RT = retention time (b) (4)

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



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

Test	Acceptance Criteria	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	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)		N/A	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)							
Cholesterol			N/A	N/A	N/A	N/A		
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)	(b) (4)				(b) (4)		
Cholesterol				N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
			(b) (4)					
		(b) (4)	(b) (4)	(b) (4)				
Mean particle size by DLS								
Polydispersity by DLS								
pH				N/A	N/A			
Osmolality			N/A	N/A	N/A	N/A		
In Vitro Translation			(b) (4)	N/A	N/A	(b) (4)		
Particulate matter			N/A	N/A	N/A	N/A		
Container content			N/A	N/A	N/A	N/A		
Bacterial endotoxin			N/A	N/A	N/A	N/A		
Sterility			N/A	N/A	N/A	N/A		

N/A = not required per the stability protocol;

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

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

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

Test	Reference Criteria (Intended Storage -15°C to -25°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
Identification by RT/ Sanger Sequencing	(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)		N/A	N/A
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				

N/A = not required per the stability protocol;

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

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

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

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	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)		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)		N/A	N/A	N/A					
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)	N/A	(b) (4)					
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD										
Mean particle size by DLS			(b) (4)	(b) (4)	(b) (4)					
Polydispersity by DLS										
pH				N/A						
Osmolality				N/A	N/A					
In Vitro Translation				N/A	(b) (4)					
Particulate matter			N/A	N/A	N/A					
Container content			N/A	N/A	N/A					
Bacterial endotoxin			N/A	N/A	N/A					
Sterility			N/A	N/A	N/A					

N/A = not required per the stability protocol;

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

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

**Table 16: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520003 (0.20 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition)**

Test	Acceptance Criteria	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	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)		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)							
Cholesterol			N/A	N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)		(b) (4)			
Cholesterol				N/A				
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)	(b) (4)	(b) (4)			
Polydispersity by DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation			(b) (4)	N/A	(b) (4)			
Particulate matter			N/A	N/A	N/A			
Container content			N/A	N/A	N/A			
Bacterial endotoxin			N/A	N/A	N/A			
Sterility			N/A	N/A	N/A			

N/A = not required per the stability protocol;

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

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

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

Test	Acceptance Criteria	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	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)		N/A	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)							
Cholesterol			N/A	N/A	N/A	N/A		
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)			(b) (4)		
Cholesterol				N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD								
Mean particle size by DLS			(b) (4)	(b) (4)				
Polydispersity by DLS								
pH			N/A	N/A	N/A	N/A		
Osmolality			N/A	N/A	N/A	N/A		
In Vitro Translation			(b) (4)	N/A	N/A	(b) (4)		
Particulate matter			N/A	N/A	N/A	N/A		
Container content			N/A	N/A	N/A	N/A		
Bacterial endotoxin			N/A	N/A	N/A	N/A		
Sterility			N/A	N/A	N/A	N/A		

N/A = not required per the stability protocol;

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

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

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

Test	Reference Criteria (Intended Storage -15°C to -25°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
Identification by RT/ Sanger Sequencing	(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)		N/A	N/A
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid content by UPLC-CAD	(b) (4)	(b) (4)		
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid impurities by UPLC-CAD				
Mean particle size by DLS	(b) (4)	(b) (4)		
Polydispersity by DLS				
pH				
In Vitro Translation				

kDa = kilodalton; RT = retention time; (b) (4)  
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is (b) (4)

**Table 19: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between -60°C to -90°C**

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	White to off-white dispersion, essentially free of particulates						
Identification by RT/ Sanger Sequencing	(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)		N/A	N/A						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)							
Cholesterol				N/A						
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD				N/A						
Mean particle size by DLS				(b) (4)						
Polydispersity by DLS										
pH				N/A						
Osmolality				N/A						
In Vitro Translation			(b) (4)	N/A						
Particulate matter			N/A	N/A						
Container content			N/A	N/A						
Bacterial endotoxin			N/A	N/A						
Sterility			N/A	N/A						

N/A = not required per the stability protocol;

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

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

**Table 20: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition)**

Test	Acceptance Criteria	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	White to off-white dispersion, essentially free of particulates				
Identification by RT/ Sanger Sequencing	(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)		N/A	N/A				
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol				N/A				
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD				N/A				
Mean particle size by DLS				(b) (4)				
Polydispersity by DLS								
pH				N/A				
Osmolality			N/A	N/A				
In Vitro Translation			(b) (4)	N/A				
Particulate matter			N/A	N/A				
Container content			N/A	N/A				
Bacterial endotoxin			N/A	N/A				
Sterility			N/A	N/A				

N/A = not required per the stability protocol;

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

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



**Table 21: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between 2°C to 8°C**

Test	Acceptance Criteria	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	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)		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)							
Cholesterol			N/A	N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)	(b) (4)	(b) (4)		N/A	N/A		
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD					N/A	N/A		
Mean particle size by DLS		(b) (4)		(b) (4)				
Polydispersity by DLS								
pH					N/A	N/A		
Osmolality			N/A	N/A	N/A			
In Vitro Translation			(b) (4)	N/A	N/A			
Particulate matter			N/A	N/A	N/A			
Container content			N/A	N/A	N/A			
Bacterial endotoxin			N/A	N/A	N/A			
Sterility			N/A	N/A	N/A			

N/A = not required per the stability protocol;

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

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

**Table 22: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between 23°C to 27°C**

Test	Reference Criteria (Intended Storage -15°C to -25°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
Identification by RT/ Sanger Sequencing	(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	(b) (4)			
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid content by UPLC-CAD	(b) (4)			
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
Lipid impurities by UPLC-CAD				
Mean particle size by DLS				
Polydispersity by DLS				
pH				
In Vitro Translation				

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

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

**Table 23: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520005 (0.20 mg/mL) Stored Between -60°C to -90°C**

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	White to off-white dispersion, essentially free of particulates						
Identification by RT/ Sanger Sequencing	(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)		N/A	N/A						
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			N/A	N/A						
In Vitro Translation			(b) (4)							
Particulate matter			N/A	N/A						
Container content			N/A	N/A						
Bacterial endotoxin			N/A	N/A						
Sterility			N/A	N/A						

N/A = not required per the stability protocol;

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

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

**Table 24: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520005 (0.20 mg/mL) Stored Between -60°C to -90°C for 1 Month / then Stored Between 2°C to 8°C**

Test	Acceptance Criteria	0	1 month	2 month	11 Weeks	3month
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)		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)		N/A			
Cholesterol						
DSPC						
PEG2000-DMG						
Lipid content by UPLC-CAD						
SM102	(b) (4)		N/A			
Cholesterol						
DSPC						
PEG2000-DMG						
Lipid impurities by UPLC-CAD			N/A			
Mean particle size by DLS			(b) (4)			
Polydispersity by DLS						
pH			N/A			
Osmolality			N/A			
In Vitro Translation			N/A			
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 acceptance criteria for purity by RP-HPLC is (b) (4)

**Table 25: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520006 (0.20 mg/mL) Stored Between -60°C to -90°C**

Test	Reference Criteria (Intended Storage -15°C to -25°C)	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	White to off-white dispersion, essentially free of particulates						
Identification by RT/ Sanger Sequencing	(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)		N/A	N/A						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		N/A	(b) (4)						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD			N/A							
Mean particle size by DLS			(b) (4)							
Polydispersity by DLS										
pH										
Osmolality			N/A	N/A						
In Vitro Translation			(b) (4)							
Particulate matter			N/A	N/A						
Container content			N/A	N/A						
Bacterial endotoxin			N/A	N/A						
Sterility			N/A	N/A						

N/A = not required per the stability protocol;

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

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

**Table 26: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520006 (0.20 mg/mL) Stored Between -60°C to -90°C for 1 Month / then Stored Between 2°C to 8°C**

Test	Acceptance Criteria	0	1 month	2 month	11 Weeks	3 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)		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)					
Cholesterol			N/A			
DSPC						
PEG2000-DMG						
Lipid content by UPLC-CAD						
SM102	(b) (4)					
Cholesterol			N/A			
DSPC						
PEG2000-DMG						
Lipid impurities by UPLC-CAD			N/A			
Mean particle size by DLS			(b) (4)			
Polydispersity by DLS						
pH			N/A			
Osmolality			N/A			
In Vitro Translation			N/A			
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 acceptance criteria for purity by RP-HPLC is (b) (4)

### 3.2.P.8.3.3 Freeze/ Thaw Cycling Data for mRNA-1273 Drug Product

**Table 27: Freeze/ Thaw Cycling Data for mRNA-1273 Drug Product, 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 28: Freeze/ Thaw Cycling Data for mRNA-1273 Drug Product, 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 29: Freeze/ Thaw Cycling Data for mRNA-1273 Drug Product, 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 30: Freeze/ Thaw Cycling Data for mRNA-1273 Drug Product, 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 Drug Product

**Table 31: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6006820001, 0.10 mg /mL, (b) (4) Unopened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h					
	Initial	T8h and T24h		RT	5°C	RT	5°C				
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											
% 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								(b) (4)		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 32: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,  
Lot 6006820001, 0.10 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5°C	RT	5°C
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							
% 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							
Osmolality							

\* 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 33: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,  
Lot 6006820001, 0.10 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5°C	RT	5°C
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							
% RNA encapsulation by (b) (4)							
Mean particle size by Dynamic light scattering	(b) (4)						
Polydispersity by Dynamic light scattering							
Lipid content by UPLC-CAD	Report result						
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 34: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product**  
**Lot 6006920001, 0.5 mg /mL, (b) (4)**  
**Unopened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h	
	Initial	T8h and T24h		RT	5°C	RT	5°C
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							
% RNA encapsulation by (b) (4)							
Mean particle size by Dynamic light scattering	(b) (4)						
Polydispersity by Dynamic light scattering						Report result	
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 35: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,  
Lot 6006920001, 0.5 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h					
	Initial	T8h and T24h		RT	5°C	RT	5°C				
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											
% 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.

ND = not detected

N/A = not required per the stability protocol

(b) (4)

**Table 36: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,  
Lot 6006920001, 0.5 mg /mL, (b) (4)  
Post 6 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 8h		T = 24h						
	Initial	T8h and T24h		RT	5°C	RT	5°C					
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												
% 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.

ND = not detected

N/A = not required per the stability protocol

(b) (4)



**Table 37: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6007520007, 0.20 mg/mL, Slip-Tip (b) (4), Post-7 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 4h		T = 8h		T = 12h	
	Initial	T4h, T8h, T12h		RT	5°C	RT	5°C	RT	5°C
Purity by RP-HPLC	(b) (4)								
Product related impurities by RP-HPLC									
In Vitro Relative Protein Expression <sup>a</sup>									
% RNA encapsulation by (b) (4)									
Mean particle size by Dynamic light scattering									
Polydispersity by Dvnmatic light scattering									

\* Initial (T = 0) results refer to doses extracted after vials were removed from -70°C storage, allowed to thaw for 1 hour at 25°C, (b) (4), and then held at room temperature for another 7 hours

N/A = not required per the stability protocol

a) All relative protein expression absolute values originally reported were artificially low due to an error on the reference material label for concentration, determined after testing was performed. A correction factor of (b) (4) was applied to this full dataset.

**Table 38: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6007520007, 0.20 mg/mL, Luer-Lok (b) (4), Post-7 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 4h		T = 8h		T = 12h	
	Initial	T4h, T8h, T12h		RT	5°C	RT	5°C	RT	5°C
Purity by RP-HPLC	(b) (4)								
Product related impurities by RP-HPLC									
In Vitro Relative Protein Expression <sup>a</sup>									
% RNA encapsulation by (b) (4)									
Mean particle size by Dynamic light scattering									
Polydispersity by Dynamic light scattering									

\* Initial (T = 0) results refer to doses extracted after vials were removed from -70°C storage, allowed to thaw for 1 hour at 25°C, (b) (4), and then held at room temperature for another 7 hours

N/A = not required per the stability protocol

a) All relative protein expression absolute values originally reported were artificially low due to an error on the reference material label for concentration, determined after testing was performed. A correction factor of (b) (4) was applied to this full dataset.

**Table 39: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,  
Lot 6007520007, 0.20 mg/mL, Slip-Tip (b) (4)  
Post-7 Hour Hold of Opened Multiple-Dose Vial**

Test	Acceptance Criteria		Initial*	T = 4h		T = 8h		T = 12h	
	Initial	T4h, T8h, T12h		RT	5°C	RT	5°C	RT	5°C
Purity by RP-HPLC	(b) (4)								
Product related impurities by RP-HPLC									
In Vitro Relative Protein Expression <sup>a</sup>									
% RNA encapsulation by (b) (4)									
Mean particle size by Dynamic light scattering									
Polydispersity by Dynamic light scattering									

\* Initial (T = 0) results refer to doses extracted after vials were removed from -70°C storage, allowed to thaw for 1 hour at 25°C, (b) (4), and then held at room temperature for another 7 hours

N/A = not required per the stability protocol

a) All relative protein expression absolute values originally reported were artificially low due to an error on the reference material label for concentration, determined after testing was performed. A correction factor of (b) (4) was applied to this full dataset.