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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](#).

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

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

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

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

The clinical in-use stability results for mRNA-1273 Drug Product, Lot 6007520007 (0.20 mg/mL) is provided in [Table 29](#) to [Table 31](#).

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							
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	(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)	(b) (4)							
Polydispersity by Dynamic light scattering											
pH											
In Vitro Translation											
Osmolality											
Particulate matter	(b) (4)		N/A	N/A							
Bacterial endotoxin											
Bioburden											

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

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	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						
Mean particle size by Dynamic light scattering	(b) (4)								
Polydispersity by Dynamic light scattering	Report result	(b) (4)							
pH	(b) (4)			N/A					
In Vitro Translation				N/A					
Osmolality				N/A					
Particulate matter				N/A					
Bacterial endotoxin				N/A					
Bioburden				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)	(b) (4)	N/A	N/A	N/A	N/A	N/A	
RNA content by AEX-HPLC	(b) (4)					N/A	N/A	
Purity by RP-HPLC						(b) (4)		
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	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	(b) (4)		N/A			N/A	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)		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	(b) (4)		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.

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						
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						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)	N/A						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD				N/A						
			(b) (4)	(b) (4)						
Mean particle size by DLS										
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 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					
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					
Cholesterol									
DSPC									
PEG2000-DMG									
Lipid content by UPLC-CAD									
SM102	(b) (4)		(b) (4)	N/A					
Cholesterol									
DSPC									
PEG2000-DMG									
Lipid impurities by UPLC-CAD					N/A				
Mean particle size by DLS		(b) (4)	(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 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			
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A	N/A			
RNA content by AEX-HPLC	(b) (4)			N/A	N/A			
Purity by RP-HPLC				(b) (4)				
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)				N/A	N/A			
Lipid identification by UPLC-CAD		(b) (4)						
SM102	(b) (4)							
Cholesterol				N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)					
Cholesterol				N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD				N/A	N/A			
			(b) (4)					
Mean particle size by DLS				(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 10: Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520001 (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)	(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	(b) (4)			
Mean particle size by DLS	(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 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						
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						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)	N/A						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD				N/A						
Mean particle size by DLS			(b) (4)	(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 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				
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				
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)	N/A				
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD	(b) (4)		(b) (4)	N/A				
Mean particle size by DLS								
Polydispersity by DLS								
pH								
Osmolality								
In Vitro Translation								
Particulate matter								
Container content								
Bacterial endotoxin								
Sterility								

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			
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A	N/A			
RNA content by AEX-HPLC	(b) (4)			N/A	N/A			
Purity by RP-HPLC				(b) (4)				
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)				N/A	N/A			
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol				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				N/A	N/A			
		(b) (4)						
Mean particle size by DLS				(b) (4)				
Polydispersity by DLS								
pH				N/A	N/A			
Osmolality				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 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)	(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	(b) (4)			
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						
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						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid content by UPLC-CAD										
SM102	(b) (4)		(b) (4)	N/A						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD				N/A						
Mean particle size by DLS			(b) (4)	(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 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				
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				
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(b) (4)		(b) (4)	N/A				
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD				N/A				
			(b) (4)					
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 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			
Identification by RT/ Sanger Sequencing	(b) (4)	(b) (4)	N/A	N/A	N/A			
RNA content by AEX-HPLC	(b) (4)			N/A	N/A			
Purity by RP-HPLC				(b) (4)				
Product related impurities by RP-HPLC								
% RNA encapsulation by (b) (4)				N/A	N/A			
Lipid identification by UPLC-CAD								
SM102	(b) (4)	(b) (4)						
Cholesterol				N/A	N/A			
DSPC								
PEG2000-DMG								
Lipid content by UPLC-CAD								
SM102	(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			
Osmolality				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 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)	(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)		
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				

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 19: 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 20: 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 21: 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 22: 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 23: 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								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 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							
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.

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 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						(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 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								
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 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	Report result									
Polydispersity by Dynamic light scattering						(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 28: 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								
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 29: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,
Lot 6007520007, 0.20 mg/mL, (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									
% RNA encapsulation by (b) (4)									
Mean particle size by <u>Dynamic light scattering</u>									
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

**Table 30: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,
Lot 6007520007, 0.20 mg/mL, (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									
% 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

**Table 31: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product,
Lot 6007520007, 0.20 mg/mL, (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									
% 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