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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	Sequence matches description	Conforms	N/A	N/A	N/A						
RNA content by AEX-HPLC	[redacted]	[redacted]	N/A	[redacted]	N/A						
Purity by RP-HPLC	[redacted]main peak area	[redacted]									
Product-related impurities by RP-HPLC	Report % Impurity group 1	[redacted]									
	Report % Impurity group 2										
	Report % Impurity group 3										
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]										
Lipid identification by UPLC-CAD											
SM102	Matches RT of standard	Conforms	N/A	Conforms	N/A						
Cholesterol	Matches RT of standard	Conforms		Conforms							
DSPC	Matches RT of standard	Conforms		Conforms							
PEG2000-DMG	Matches RT of standard	Conforms		Conforms							
Lipid content by UPLC-CAD											
SM102	[redacted]	[redacted]	N/A	[redacted]	N/A						
Cholesterol											
DSPC											
PEG2000-DMG											
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT % Area [redacted]	N/A	RRT % Area [redacted]	N/A						
	Report % Area of Total Impurities	Total [redacted]		Total [redacted]							
Mean particle size by Dynamic light scattering	[redacted]										
Polydispersity by Dynamic light scattering	Report result	[redacted]									
pH	[redacted]		N/A	[redacted]							
In Vitro Translation			N/A	[redacted]	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; RRT = relative retention time;
*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	Sequence matches description	Conforms		N/A	N/A		N/A					
RNA content by AEX-HPLC	[redacted]			N/A	[redacted]							
Purity by RP-HPLC	[redacted] main peak area	[redacted]										
Product-related impurities by RP-HPLC	Report % Impurity group 1											
	Report % Impurity group 2											
	Report % Impurity group 3											
% RNA encapsulation by RiboGreen (Fluorescence)												
Lipid identification by UPLC-CAD												
SM102	Matches RT of standard	Conforms		N/A	Conforms		Conforms					
Cholesterol	Matches RT of standard	Conforms		N/A	Conforms		Conforms					
DSPC	Matches RT of standard	Conforms		N/A	Conforms		Conforms					
PEG2000-DMG	Matches RT of standard	Conforms		N/A	Conforms		Conforms					
Lipid content by UPLC-CAD												
SM102	[redacted]			N/A	[redacted]							
Cholesterol				N/A								
DSPC				N/A								
PEG2000-DMG				N/A								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT	% Area	N/A	RRT	% Area	RRT	% Area				
		[redacted]			[redacted]		[redacted]					
	Report % Area of Total Impurities	Total	[redacted]		Total	[redacted]	Total	[redacted]				
Mean particle size by Dynamic light scattering	[redacted]											
Polydispersity by Dynamic light scattering	Report result	[redacted]										
pH	[redacted]			N/A	[redacted]							
In Vitro Translation	[redacted]			N/A	[redacted]							
Osmolality				N/A	N/A		N/A					
Particulate matter				N/A	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;
RRT = relative retention time

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	Sequence matches description	Conforms		N/A	N/A		N/A		N/A	N/A
RNA content by AEX-HPLC	[redacted]			N/A	[redacted]				N/A	N/A
Purity by RP-HPLC	[redacted] main peak area	[redacted]		[redacted]						
Product related impurities by RP-HPLC	Report % Impurity group 1									
	Report % Impurity group 2									
	Report % Impurity group 3									
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]									
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
Cholesterol	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
DSPC	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
PEG2000-DMG	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
Lipid content by UPLC-CAD										
SM102	[redacted]			N/A	[redacted]				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	Report RRT and % Area for individual impurities	RRT	% Area	N/A	RRT	N/A	RRT	% Area	N/A	N/A
		[redacted]			[redacted]					
	Report % Area of Total Impurities	Total	[redacted]		Total	[redacted]	Total	[redacted]		
Mean particle size by Dynamic light scattering	[redacted]									
Polydispersity by Dynamic light scattering	Report result	[redacted]								
pH	[redacted]			N/A	[redacted]				N/A	N/A
In Vitro Translation				N/A					N/A	N/A
Osmolality	[redacted]			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; RRT = relative retention time;

*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	Sequence matches description	Conforms	N/A	N/A	N/A						
RNA content by AEX-HPLC	[redacted]	[redacted]	N/A	[redacted]	N/A						
Purity by RP-HPLC	[redacted] main peak area	[redacted]	[redacted]	[redacted]	[redacted]						
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]						
Lipid identification by UPLC-CAD											
SM102	Matches RT of standard	Conforms	N/A	Conforms	Conforms						
Cholesterol	Matches RT of standard	Conforms	N/A	Conforms	Conforms						
DSPC	Matches RT of standard	Conforms	N/A	Conforms	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms	N/A	Conforms	Conforms						
Lipid content by UPLC-CAD											
SM102	[redacted]	[redacted]	N/A	[redacted]	[redacted]						
Cholesterol	[redacted]	[redacted]	N/A	[redacted]	[redacted]						
DSPC	[redacted]	[redacted]	N/A	[redacted]	[redacted]						
PEG2000-DMG	[redacted]	[redacted]	N/A	[redacted]	[redacted]						
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area [redacted]	N/A	RRT / % Area [redacted]	No impurities detected [redacted]						
	Report % Area of Total Impurities	Total [redacted]		Total [redacted]							
Mean particle size by Dynamic light scattering	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]						
Polydispersity by Dynamic light scattering	Report result	[redacted]	[redacted]	[redacted]	[redacted]						
pH	[redacted]	[redacted]	N/A	[redacted]	[redacted]						
In Vitro Translation	[redacted]	[redacted]	N/A	[redacted]	N/A						
Osmolality	[redacted]	[redacted]	N/A	N/A	N/A						
Particulate matter	[redacted]	[redacted]	N/A	N/A	N/A N/A						
Bacterial endotoxin	[redacted]	[redacted]	N/A	N/A	N/A						
Bioburden	[redacted]	[redacted]	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; RRT = relative retention time;
*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	Sequence matches description	Conforms	N/A	N/A	N/A				
RNA content by AEX-HPLC	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
Purity by RP-HPLC	[redacted]ain peak area	[redacted]	[redacted]	[redacted]	[redacted]				
Product-related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]				
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]				
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]				
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
Lipid identification by UPLC-CAD									
SM102	Matches RT of standard	Conforms	N/A	Conforms	Conforms				
Cholesterol	Matches RT of standard	Conforms	N/A	Conforms	Conforms				
DSPC	Matches RT of standard	Conforms	N/A	Conforms	Conforms				
PEG2000-DMG	Matches RT of standard	Conforms	N/A	Conforms	Conforms				
Lipid content by UPLC-CAD									
SM102	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
Cholesterol	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
DSPC	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
PEG2000-DMG	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area [redacted]	N/A	RRT / % Area [redacted]	No impurities detected [redacted]				
	Report % Area of Total Impurities	Total [redacted]		Total [redacted]					
Mean particle size by Dynamic light scattering	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
Polydispersity by Dynamic light scattering	Report result	[redacted]	[redacted]	[redacted]	[redacted]				
pH	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
In Vitro Translation	[redacted]	[redacted]	N/A	[redacted]	[redacted]				
Osmolality	[redacted]	[redacted]	N/A	N/A	N/A				
Particulate matter	[redacted]	[redacted]	N/A	N/A	N/A				
					N/A				
Bacterial endotoxin	[redacted]	[redacted]	N/A	N/A	N/A				
Bioburden	[redacted]	[redacted]	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; RRT = relative retention time;

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	Sequence matches description	Conforms		N/A	N/A		N/A		N/A	N/A
RNA content by AEX-HPLC	[redacted]	[redacted]		N/A	0.4		0.4		N/A	N/A
Purity by RP-HPLC	[redacted] main peak area	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
	Report % Impurity group 2	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
	Report % Impurity group 3	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
Cholesterol	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
DSPC	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
PEG2000-DMG	Matches RT of standard	Conforms		N/A	Conforms		Conforms		N/A	N/A
Lipid content by UPLC-CAD										
SM102	[redacted]	[redacted]		N/A	[redacted]		[redacted]		N/A	N/A
Cholesterol	[redacted]	[redacted]		N/A	[redacted]		[redacted]		N/A	N/A
DSPC	[redacted]	[redacted]		N/A	[redacted]		[redacted]		N/A	N/A
PEG2000-DMG	[redacted]	[redacted]		N/A	[redacted]		[redacted]		N/A	N/A
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT	% Area	N/A	RRT	% Area	RRT	% Area	N/A	N/A
		[redacted]	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]		
	Report % Area of Total Impurities	Total	[redacted]		Total	[redacted]	Total	[redacted]		
Mean particle size by Dynamic light scattering	[redacted]	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
Polydispersity by Dynamic light scattering	Report result	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	[redacted]
pH	[redacted]	[redacted]		N/A	[redacted]		[redacted]		N/A	N/A
In Vitro Translation	[redacted]	[redacted]		N/A	[redacted]		[redacted]		N/A	N/A
Osmolality	[redacted]	[redacted]		N/A	N/A		N/A		N/A	N/A
Particulate matter	[redacted]	[redacted]		N/A	N/A		N/A		N/A	N/A
Bacterial endotoxin	[redacted]	[redacted]		N/A	N/A		N/A		N/A	N/A
Bioburden	[redacted]	[redacted]		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; RRT = relative retention time;
*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	White to off-white dispersion, essentially free of particulates					
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A					
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	[redacted]					
Purity by RP-HPLC	[redacted] main peak area [a]	[redacted]	[redacted]	[redacted]	[redacted]					
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]					
	Report % Impurity group 2									
	Report % Impurity group 3									
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]					
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A					
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]			N/A	[redacted]					
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]					
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]		Total [redacted]					
Mean particle size by DLS	[redacted]			[redacted]						
Polydispersity by DLS										
pH				N/A	[redacted]					
Osmolality			N/A	N/A	N/A					
In Vitro Translation			[redacted]	N/A	[redacted]					
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	No Growth	No Growth	N/A	N/A	N/A					

N/A = not required per the stability protocol; kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A			
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]	[redacted]			
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]			
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]			
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]			
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A			
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]			
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]		Total [redacted]			
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
Polydispersity by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
pH	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Osmolality	[redacted]	[redacted]	N/A	N/A	N/A			
In Vitro Translation	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Particulate matter	[redacted]	[redacted]	N/A	N/A	N/A			
Container content	[redacted]	[redacted]	N/A	N/A	N/A			
Bacterial endotoxin	[redacted]	[redacted]	N/A	N/A	N/A			
Sterility	No Growth	No Growth	N/A	N/A	N/A			

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A	N/A		
RNA content by AEX-HPLC	[redacted]			N/A	N/A	[redacted]		
Purity by RP-HPLC	[redacted] main peak area[(a)]	[redacted]						
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]						
	Report % Impurity group 2							
	Report % Impurity group 3							
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]			N/A	N/A	[redacted]		
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A	N/A		
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]			N/A	N/A	[redacted]		
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD		RRT / % Area	RRT / % Area			RRT / % Area		
	Report RRT and % Area for individual impurities	[redacted]	[redacted]	N/A	N/A	[redacted]		
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]			Total [redacted]		
Mean particle size by DLS	[redacted]			[redacted]		[redacted]		
Polydispersity by DLS								
pH				N/A	N/A			
Osmolality			N/A	N/A	N/A	N/A		
In Vitro Translation			[redacted]	N/A	N/A	[redacted]		
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	No Growth	No Growth	N/A	N/A	N/A	N/A		

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted].

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	Sequence matches description	Conforms		N/A		N/A	
RNA content by AEX-HPLC	[redacted]	[redacted]					
Purity by RP-HPLC	[redacted]main peak area[a]						
Product related impurities by RP-HPLC	Report % Impurity group 1						
	Report % Impurity group 2						
	Report % Impurity group 3						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]						
Lipid identification by UPLC-CAD							
SM102	Matches RT of standard	Conforms		N/A		N/A	
Cholesterol	Matches RT of standard	Conforms					
DSPC	Matches RT of standard	Conforms					
PEG2000-DMG	Matches RT of standard	Conforms					
Lipid content by UPLC-CAD							
SM102	[redacted]						
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT	% Area	RRT	% Area	RRT	% Area
		[redacted]					
	Report % Area of Total Impurities	Total		Total		Total	
Mean particle size by DLS	[redacted]						
Polydispersity by DLS							
pH							
In Vitro Translation							

kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A					
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	[redacted]					
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]	[redacted]					
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]					
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]					
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]					
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]					
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A					
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]	[redacted]	[redacted]	N/A	[redacted]					
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]					
	Report % Area of Total Impurities	Total: [redacted]	Total: [redacted]		Total: [redacted]					
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]					
Polydispersity by DLS										
pH				N/A						
Osmolality			N/A	N/A	N/A					
In Vitro Translation			[redacted]	N/A	[redacted]					
Particulate matter	[redacted]	[redacted]	N/A	N/A	N/A					
Container content			N/A	N/A	N/A					
Bacterial endotoxin			N/A	N/A	N/A					
Sterility	No Growth	No Growth	N/A	N/A	N/A					

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A			
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Purity by RP-HPLC	[redacted] main peak area[(a)]	[redacted]	[redacted]	[redacted]	[redacted]			
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]			
	Report % Impurity group 2							
	Report % Impurity group 3							
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A			
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]			
	Report % Area of Total Impurities	Total: [redacted]	Total: [redacted]		Total: [redacted]			
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
Polydispersity by DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation			[redacted]	N/A	[redacted]			
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	No Growth	No Growth	N/A	N/A	N/A			

N/A = not required per the stability protocol;
kDa = kilodalton;
RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A	N/A		
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Purity by RP-HPLC	[redacted]ain peak area[a]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A	N/A		
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	N/A	RRT / % Area: [redacted]		
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]			Total [redacted]		
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
Polydispersity by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
pH	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Osmolality	[redacted]	[redacted]	N/A	N/A	N/A	N/A		
In Vitro Translation	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Particulate matter	[redacted]	[redacted]	N/A	N/A	N/A	N/A		
Container content	[redacted]	[redacted]	N/A	N/A	N/A	N/A		
Bacterial endotoxin	[redacted]	[redacted]	N/A	N/A	N/A	N/A		
Sterility	No Growth	No Growth	N/A	N/A	N/A	N/A		

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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-wbite dispersion, essentially free of particulates		White to off-white dispersion, essentially free of particulates		White to off-wbite dispersion, essentially free of particulates	
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms		N/A		N/A	
RNA content by AEX-HPLC	[redacted]	[redacted]					
Purity by RP-HPLC	[redacted] main peak area[a]						
Product related impurities by RP-HPLC	Report % Impurity group 1						
	Report % Impurity group 2						
	Report % Impurity group 3						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]						
Lipid identification by UPLC-CAD							
SM102	Matches RT of standard	Conforms		N/A		N/A	
Cholesterol	Matches RT of standard	Conforms					
DSPC	Matches RT of standard	Conforms					
PEG2000-DMG	Matches RT of standard	Conforms					
Lipid content by UPLC-CAD							
SM102	[redacted]						
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT	% Area	RRT	% Area	RRT	% Area
		[redacted]					
	Report % Area of Total Impurities	Total		Total		Total	
Mean particle size by DLS	[redacted]						
Polydispersity by DLS							
pH							
In Vitro Translation							

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A					
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	[redacted]					
Purity by RP-HPLC	[redacted]main peak area[a]	[redacted]	[redacted]	[redacted]	[redacted]					
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]					
	Report % Impurity group 2									
	Report % Impurity group 3									
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]					
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A					
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]	[redacted]	[redacted]	N/A	[redacted]					
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]					
	Report % Area of Total Impurities	Total: [redacted]	Total: [redacted]		Total: [redacted]					
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]					
Polydispersity by DLS										
pH				N/A						
Osmolality			N/A	N/A	N/A					
In Vitro Translation			[redacted]	N/A	[redacted]					
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	No Growth	No Growth	N/A	N/A	N/A					

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A			
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]	[redacted]			
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]			
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]			
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]			
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A			
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]	[redacted]	[redacted]	N/A	[redacted]			
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]			
	Report % Area of Total Impurities	Total: [redacted]	Total: [redacted]		Total: [redacted]			
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
Polydispersity by DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation			[redacted]	N/A	[redacted]			
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	No Growth	No Growth	N/A	N/A	N/A			

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A	N/A	N/A		
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A	N/A	N/A		
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]	[redacted]	[redacted]	N/A	N/A	[redacted]		
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area	RRT / % Area	N/A	N/A	RRT / % Area		
		[redacted]	[redacted]			[redacted]		
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]			Total [redacted]		
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
Polydispersity by DLS								
pH				N/A	N/A			
Osmolality			N/A	N/A	N/A	N/A		
In Vitro Translation			[redacted]	N/A	N/A	[redacted]		
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	No Growth	No Growth	N/A	N/A	N/A	N/A		

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted].

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-wbite dispersion. May contain visible, white or translucent product-related particulates	White to off-wbite 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	Sequence matches description	Conforms		N/A		N/A	
RNA content by AEX-HPLC	[redacted]	[redacted]					
Purity by RP-HPLC	[redacted] main peak area						
Product related impurities by RP-HPLC	Report % Impurity group 1						
	Report % Impurity group 2						
	Report % Impurity group 3						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]						
Lipid identification by UPLC-CAD							
SM102	Matches RT of standard	Conforms		N/A		N/A	
Cholesterol	Matches RT of standard	Conforms					
DSPC	Matches RT of standard	Conforms					
PEG2000-DMG	Matches RT of standard	Conforms					
Lipid content by UPLC-CAD							
SM102	[redacted]						
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT	% Area	RRT	% Area	RRT	% Area
		[redacted]					
	Report % Area of Total Impurities	Total		Total		Total	
Mean particle size by DLS	[redacted]						
Polydispersity by DLS							
pH							
In Vitro Translation							

kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A						
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A						
Purity by RP-HPLC	[redacted]main peak area[a]	[redacted]	[redacted]	[redacted]						
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 2									
	Report % Impurity group 3									
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]						
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms	N/A	N/A						
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]	[redacted]	[redacted]	N/A						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area	RRT / % Area	N/A						
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]							
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]						
Polydispersity by DLS										
pH				N/A						
Osmolality			N/A	N/A						
In Vitro Translation			[redacted]	N/A						
Particulate matter			N/A	N/A						
Container content			N/A	N/A						
Bacterial endotoxin			N/A	N/A						
Sterility	No Growth	No Growth	N/A	N/A						

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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	Sequence matches description	Conforms	N/A	N/A				
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	N/A				
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]				
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]				
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]				
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]				
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]				
Lipid identification by UPLC-CAD								
SM102	Matches RT of standard	Conforms	N/A	N/A				
Cholesterol	Matches RT of standard	Conforms						
DSPC	Matches RT of standard	Conforms						
PEG2000-DMG	Matches RT of standard	Conforms						
Lipid content by UPLC-CAD								
SM102	[redacted]	[redacted]	[redacted]	N/A				
Cholesterol								
DSPC								
PEG2000-DMG								
Lipid impurities by UPLC-CAD		RRT / % Area	RRT / % Area	N/A				
	Report RRT and % Area for individual impurities	[redacted]	[redacted]					
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]					
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]				
Polydispersity by DLS	[redacted]	[redacted]	[redacted]	[redacted]				
pH	[redacted]	[redacted]	[redacted]	N/A				
Osmolality	[redacted]	[redacted]	N/A	N/A				
In Vitro Translation	[redacted]	[redacted]	[redacted]	N/A				
Particulate matter	[redacted]	[redacted]	N/A	N/A				
Container content	[redacted]	[redacted]	N/A	N/A				
Bacterial endotoxin	[redacted]	[redacted]	N/A	N/A				
Sterility	No Growth	No Growth	N/A	N/A				

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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	Sequence matches description	Conforms		N/A		N/A	N/A			
RNA content by AEX-HPLC	[redacted]	[redacted]				N/A	N/A			
Purity by RP-HPLC	[redacted] main peak area[a]					[redacted]				
Product related impurities by RP-HPLC	Report % Impurity group 1									
	Report % Impurity group 2									
	Report % Impurity group 3									
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]					N/A	N/A			
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms		N/A		N/A	N/A			
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]					N/A	N/A			
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD		RRT	% Area	RRT	% Area					
	Report RRT and % Area for individual impurities	[redacted]		[redacted]		N/A	N/A			
	Report % Area of Total Impurities	Total	[redacted]	Total	[redacted]					
Mean particle size by DLS	[redacted]									
Polydispersity by DLS										
pH						N/A	N/A			
Osmolality				N/A		N/A	N/A			
In Vitro Translation				[redacted]		N/A	N/A			
Particulate matter	[redacted]			N/A		N/A	N/A			
Container content				N/A		N/A	N/A			
Bacterial endotoxin				N/A		N/A	N/A			
Sterility	No Growth	No Growth		N/A		N/A	N/A			

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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-wbite dispersion. May contain visible, white or translucent product-related particulates	White to off-wbite 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	Sequence matches description	Conforms		N/A		N/A	
RNA content by AEX-HPLC	[redacted]	[redacted]					
Purity by RP-HPLC	[redacted] main peak area						
Product related impurities by RP-HPLC	Report % Impurity group 1						
	Report % Impurity group 2						
	Report % Impurity group 3						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]						
Lipid identification by UPLC-CAD							
SM102	Matches RT of standard	Conforms		N/A			
Cholesterol	Matches RT of standard	Conforms					
DSPC	Matches RT of standard	Conforms					
PEG2000-DMG	Matches RT of standard	Conforms					
Lipid content by UPLC-CAD							
SM102	[redacted]						
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT	%Area	RRT	%Area	RRT	%Area
		[redacted]					
	Report % Area of Total Impurities	Total	[redacted]	Total		Total	
Mean particle size by DLS	[redacted]						
Polydispersity by DLS							
pH							
In Vitro Translation							

kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A						
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	[redacted]						
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]						
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]						
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms	N/A	N/A						
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]	[redacted]	[redacted]	[redacted]						
Cholesterol										
DSPC										
PEG2000-DMG										
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area	RRT / % Area	RRT / % Area						
		[redacted]	[redacted]	[redacted]						
	Report % Area of Total Impurities	Total [redacted]	Total [redacted]	Total [redacted]						
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]						
Polydispersity by DLS										
pH										
Osmolality			N/A	N/A						
In Vitro Translation			[redacted]							
Particulate matter			N/A	N/A						
Container content			N/A	N/A						
Bacterial endotoxin			N/A	N/A						
Sterility	No Growth	No growth	N/A	N/A						

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A			
RNA content by AEX-HPLC	[redacted]	[redacted]	N/A			
Purity by RP-HPLC	[redacted]main peak area[a]	[redacted]	[redacted]			
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]			
	Report % Impurity group 2					
	Report % Impurity group 3					
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	N/A			
Lipid identification by UPLC-CAD						
SM102	Matches RT of standard	Conforms	N/A			
Cholesterol	Matches RT of standard	Conforms				
DSPC	Matches RT of standard	Conforms				
PEG2000-DMG	Matches RT of standard	Conforms				
Lipid content by UPLC-CAD						
SM102	[redacted]	[redacted]	N/A			
Cholesterol						
DSPC						
PEG2000-DMG						
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	N/A			
	Report % Area of Total Impurities	Total [redacted]				
Mean particle size by DLS	[redacted]	[redacted]				
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	No Growth	No growth	N/A			

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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	Sequence matches description	Conforms	N/A	N/A						
RNA content by AEX-HPLC	[redacted]	[redacted]	[redacted]	[redacted]						
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]	[redacted]						
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 2	[redacted]	[redacted]	[redacted]						
	Report % Impurity group 3	[redacted]	[redacted]	[redacted]						
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	[redacted]	[redacted]						
Lipid identification by UPLC-CAD										
SM102	Matches RT of standard	Conforms	N/A	N/A						
Cholesterol	Matches RT of standard	Conforms								
DSPC	Matches RT of standard	Conforms								
PEG2000-DMG	Matches RT of standard	Conforms								
Lipid content by UPLC-CAD										
SM102	[redacted]	[redacted]	N/A	[redacted]						
Cholesterol	[redacted]	[redacted]		[redacted]						
DSPC	[redacted]	[redacted]		[redacted]						
PEG2000-DMG	[redacted]	[redacted]		[redacted]						
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	N/A	RRT / % Area: [redacted]						
	Report % Area of Total Impurities	Total [redacted]		Total [redacted]						
Mean particle size by DLS	[redacted]	[redacted]	[redacted]	[redacted]						
Polydispersity by DLS	[redacted]	[redacted]	[redacted]	[redacted]						
pH	[redacted]	[redacted]	[redacted]	[redacted]						
Osmolality	[redacted]	[redacted]	N/A	N/A						
In Vitro Translation	[redacted]	[redacted]	[redacted]	[redacted]						
Particulate matter	[redacted]	[redacted]	N/A	N/A						
	[redacted]	[redacted]	N/A	N/A						
Container content	[redacted]	[redacted]	N/A	N/A						
Bacterial endotoxin	[redacted]	[redacted]	N/A	N/A						
Sterility	No Growth	No growth	N/A	N/A						

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥[redacted]

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	Sequence matches description	Conforms	N/A			
RNA content by AEX-HPLC	[redacted]	[redacted]	N/A			
Purity by RP-HPLC	[redacted] main peak area[a]	[redacted]	[redacted]			
Product related impurities by RP-HPLC	Report % Impurity group 1	[redacted]	[redacted]			
	Report % Impurity group 2					
	Report % Impurity group 3					
% RNA encapsulation by RiboGreen (Fluorescence)	[redacted]	[redacted]	N/A			
Lipid identification by UPLC-CAD						
SM102	Matches RT of standard	Conforms	N/A			
Cholesterol	Matches RT of standard	Conforms				
DSPC	Matches RT of standard	Conforms				
PEG2000-DMG	Matches RT of standard	Conforms				
Lipid content by UPLC-CAD						
SM102	[redacted]	[redacted]	N/A			
Cholesterol						
DSPC						
PEG2000-DMG						
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT / % Area: [redacted]	N/A			
	Report % Area of Total Impurities	Total: [redacted]				
Mean particle size by DLS	[redacted]	[redacted]	[redacted]			
Polydispersity by DLS						
pH			N/A			
Osmolality			N/A			
In Vitro Translation			N/A			
Particulate matter			N/A			
			N/A			
Container content			N/A			
Bacterial endotoxin			N/A			
Sterility	No Growth	No growth	N/A			

N/A = not required per the stability protocol;
kDa = kilodalton; RT = retention time; RRT = relative retention time
a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥ [redacted]

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 Fluorescence (RiboGreen)	[redacted]	[redacted]			
Purity by RP-HPLC	[redacted] main peak area				
Product related impurities by RP-HPLC	Report % area impurity group 1				
	Report % area impurity group 2				
	Report % area impurity group 3				
Mean particle size by Dynamic light scattering	[redacted]				
Polydispersity by Dynamic light scattering	Report result				

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 Fluorescence (RiboGreen)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Purity by RP-HPLC	[redacted] main peak area	[redacted]	[redacted]	[redacted]	[redacted]
Product related impurities by RP-HPLC	Report % area impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]
	Report % area impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]
	Report % area impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]
Mean particle size by Dynamic light scattering	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Polydispersity by Dynamic light scattering	Report result	[redacted]	[redacted]	[redacted]	[redacted]

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 Fluorescence (RiboGreen)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Purity by RP-HPLC	[redacted] main peak area	[redacted]	[redacted]	[redacted]	[redacted]
Product related impurities by RP-HPLC	Report % area impurity group 1	[redacted]	[redacted]	[redacted]	[redacted]
	Report % area impurity group 2	[redacted]	[redacted]	[redacted]	[redacted]
	Report % area impurity group 3	[redacted]	[redacted]	[redacted]	[redacted]
Mean particle size by Dynamic light scattering	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Polydispersity by Dynamic light scattering	Report result	[redacted]	[redacted]	[redacted]	[redacted]

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 Fluorescence (RiboGreen)	[redacted]	[redacted]			
Purity by RP-HPLC	[redacted] main peak area				
Product related impurities by RP-HPLC	Report % area impurity group 1				
	Report % area impurity group 2				
	Report % area impurity group 3				
Mean particle size by Dynamic light scattering	[redacted]				
Polydispersity by Dynamic light scattering	Report result				

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, (Polycarbonate) 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	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Purity by RP-HPLC	[redacted] main peak area						
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		%Area				
	Impurity Group 1		[redacted]				
	Impurity Group 2						
	Impurity Group 3						
	Total impurities						
In Vitro Translation	[redacted]						
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result						
Lipid content by UPLC-CAD							
SM-102	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)	RRT		%Area				
	RRT		[redacted]				
	RRT		ND			ND	
	RRT		ND		ND		
	RRT						
	RRT						
	RRT						
	RRT						
	RRT						
pH	[redacted]			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
RRT = relative retention time

Table 32: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6006820001, 0.10 mg /mL, (Polycarbonate) 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	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Purity by RP-HPLC	[redacted] main peak area						
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		%Area				
	Impurity Group 1		[redacted]				
	Impurity Group 2						
	Impurity Group 3						
	Total impurities						
In Vitro Translation	[redacted]						
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result						
Lipid content by UPLC-CAD							
SM-102	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)	RRT		%Area				
	RRT		[redacted]				
	RRT		ND				ND
	RRT		ND	ND	ND	[redacted]	ND
	RRT		[redacted]				
	RRT						
	RRT						
	RRT						
	RRT						
pH	[redacted]		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
RRT = relative retention time

Table 33: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6006820001, 0.10 mg /mL, (Polypropylene) 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	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Purity by RP-HPLC	[redacted]	main peak area					
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		%Area				
	Impurity Group 1		[redacted]				
	Impurity Group 2						
	Impurity Group 3						
	Total impurities						
In Vitro Translation	[redacted]						
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result						
Lipid content by UPLC-CAD							
SM-102	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)	RRT		%Area				
	RRT		[redacted]				
	RRT		ND	ND			
	RRT		ND	ND		ND	ND
	RRT		[redacted]				
	RRT						
	RRT						
	RRT						
	RRT						
pH	[redacted]		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
RRT = relative retention time

Table 34: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product Lot 6006920001, 0.5 mg /mL, (Polycarbonate) 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	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Purity by RP-HPLC	[redacted] main peak area						
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		%Area				
	Impurity Group 1		[redacted]				
	Impurity Group 2						
	Impurity Group 3						
	Total impurities						
In Vitro Translation	[redacted]						
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result						
Lipid content by UPLC-CAD							
SM-102	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)	RRT		%Area				
	RRT [redacted]		[redacted]				
	RRT						
	RRT						
	RRT						
	RRT						
pH	[redacted]		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
RRT = relative retention time

Table 35: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6006920001, 0.5 mg /mL, (Polycarbonate) 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	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Purity by RP-HPLC	[redacted]	main peak area					
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		%Area				
	Impurity Group 1		[redacted]				
	Impurity Group 2						
	Impurity Group 3						
	Total impurities						
In Vitro Translation	[redacted]		[redacted]				
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result						
Lipid content by UPLC-CAD							
SM-102	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)	RRT		%Area				
	RRT [redacted]		[redacted]				
	RRT						
	RRT						
	RRT						
	RRT						
pH	[redacted]		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
RRT = relative retention time

Table 36: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6006920001, 0.5 mg /mL, (Polypropylene) 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	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Purity by RP-HPLC	[redacted]	main peak area					
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		%Area				
	Impurity Group 1		[redacted]				
	Impurity Group 2						
	Impurity Group 3						
	Total impurities						
In Vitro Translation	[redacted]						
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Report result						
Lipid content by UPLC-CAD							
SM-102	[redacted]	% Difference from Initial is [redacted]	[redacted]				
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid impurities by UPLC-CAD (Report RRT and % Area)	RRT		%Area				
	RRT		[redacted]				
	RRT						
	RRT						
	RRT						
	RRT						
pH	[redacted]			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
RRT = relative retention time

Table 37: Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6007520007, 0.20 mg/mL, Slip-Tip (Polypropylene), 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	[redacted] main peak area		[redacted]						
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		% Area						
	Impurity Group 1		[redacted]						
	Impurity Group 2								
	Impurity Group 3								
	Total impurities								
In Vitro Relative Protein Expression [a]	Report Results			N/A					
% RNA encapsulation by Fluorescence (RiboGreen)	[redacted]								
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, punctured 4 times, 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 1.60 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 (Polycarbonate), 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	[redacted] main peak area		[redacted]						
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		% Area						
	Impurity Group 1		[redacted]						
	Impurity Group 2								
	Impurity Group 3								
	Total impurities								
In Vitro Relative Protein Expression [a]	Report Results		[redacted]	N/A				[redacted]	
% RNA encapsulation by Fluorescence (RiboGreen)	[redacted]								
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, punctured 4 times, 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 1.60 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 (Polypropylene), 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	[redacted] main peak area		[redacted]						
Product related impurities by RP-HPLC	Report %Area for each Impurity Group		% Area						
	Impurity Group 1		[redacted]						
	Impurity Group 2								
	Impurity Group 3								
	Total impurities								
In Vitro Relative Protein Expression [a]	Report Results		[redacted]	N/A				[redacted]	
% RNA encapsulation by Fluorescence (RiboGreen)	[redacted]								
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, punctured 4 times, 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 1.60 was applied to this full dataset.