### **Table of Contents**

Table of C	Contents	
List of Ta	bles2	e le
3.2.P.8.3	Stability Data4	EHRO
3.2.P.8.3.1	Stability Data for Development mRNA-1273 Drug Product5	iiON3
3,2.P.8.3.2	2 Stability Data for GMP mRNA-1273 Drug Product11	
3.2,P.8.3.3	Freeze/ Thaw Cycling Data for mRNA-1273 Drug Product31	
3.2.P.8.3.4	4 Clinical In-Use Compatibility Data for mRNA-1273 Drug Product35	
This document cannot be	Stability Data	

# List of Tables

Table 1:	Stability Results for Development mRNA-1273 Drug Product, DHM-47519 (0.10 mg/mL) Stored Between -60°C to -90°C
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) .6
Table 3:	Stability Results for Development mRNA-1273 Drug Product, DHM-47519 (0.10 mg/mL) Stored Between 2°C to 8°C
Table 4:	Stability Results for Development mRNA-1273 Drug Product, DHM-47516 (0.5 mg/mL) Stored Between -60°C to -90°C8
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)9
Table 6:	Stability Results for Development mRNA-1273 Drug Product, DHM-47516 (0.5 mg/mL) Stored Between 2°C to 8°C10
Table 7:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520001 (0.20 mg/mL) Stored Between -60°C to -90°C11
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) 12
Table 9:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520001 (0.20 mg/mL) Stored Between 2°C to 8°C13
Table 10:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520001 (0.20 mg/mL) Stored Between 23°C to 27°C
Table 11:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520002 (0.20 mg/mL) Stored Between -60°C to -90°C
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) 16
Table 13:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520002 (0.20 mg/mL) Stored Between 2°C to 8°C
Table 14:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520002 (0.20 mg/mL) Stored Between 23°C to 27°C
Table 15:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520003 (0.20 mg/mL) Stored Between -60°C to -90°C
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) 20
Table 170	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520003 (0.20 mg/mL) Stored Between 2°C to 8°C21
Table 18:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520003 (0.20 mg/mL) Stored Between 23°C to 27°C
Table 19:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between -60°C to -90°C23
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)24
Table 21:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between 2°C to 8°C
Table 22:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520004 (0.20 mg/mL) Stored Between 23°C to 27°C

Table 23:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520005 (0.20 mg/mL) Stored Between -60°C to -90°C27
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
Table 25:	Stability Results for GMP mRNA-1273 Drug Product, Lot 6007520006 (0.20 mg/mL) Stored Between -60°C to -90°C29
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
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 Temperature31
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°C32
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
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°C34
Table 31:	Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, Lot 6006820001, 0.10 mg/mL, (Polycarbonate) Unopened Multiple-Dose Vial35
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
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
Table 34:	Clinical In-Use Compatibility Data for mRNA-1273 Drug Product Lot 6006920001, 0.5 mg/mL, (Polycarbonate) Unopened Multiple-Dose Vial38
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
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
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
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
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

## 3.2.P.8.3 Stability Data

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

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

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

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

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

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

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

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

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

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

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

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

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

mRNA-1273

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

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

								<u> </u>			
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
	White to off-white dispersion. May	White to off-white	White to off-white	White to off-white	White to off-white		1979	9			
Appearance	contain visible, white or translucent	dispersion, essentially		dispersion, essentially			(A) (A)	1			
Афремансс	product-related particulates	free of particulates	free of particulates		free of particulates		(7) × "				
Identification		-	_	_	_		100 00 00 00 00 00 00 00 00 00 00 00 00				
by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A	- 1	<i>b</i>				
RNA content			NT/A		N7/A	_0_	, o.Y				
by AEX-HPLC			N/A		N/A	3,0	(V.)				
Purity by RP-HPLC	main peak area					AN A	*				
D	Report % Impurity group 1										
Product-related impurities by RP-HPLC	Report % Impurity group 2					N A					
by RP-HFIC	Report % Impurity group 3					X ()					
% RNA encapsulation						_ N					
by RiboGreen (Fluorescence)											
Lipid identification by UPLC-	CAD				D. 70, 01	3					
SM102	Matches RT of standard	Conforms		Conforms							
Cholesterol	Matches RT of standard	Conforms	37/4	Conforms (	N/A						
DSPC	Matches RT of standard	Conforms	N/A	Conforms	all On						
PEG2000-DMG	Matches RT of standard	Conforms	1	Conforms	0 /0						
Lipid content by UPLC-CAD	•		•	~D. 1/2	10						
SM102					4						
Cholesterol			27/4		,						
DSPC			N/A		N/A						
PEG2000-DMG											
		RRT % Area		RRT % Area							
				1000							
	Report RRT and % Area		~(								
Lipid impurities	for individual impurities		N/A		N/A						
by UPLC-CAD	Tor med victors impuritors		N/A		14/24						
									-		
	Report % Area of Total Impurities	Total	x '0 20	Total				-			
Mean particle size	Report 70 Area of Total Impurities	10041	10 4	10021				-			
by Dynamic light scattering											
Polydispersity											
by Dynamic light scattering	Report result										
pH			N/A								
In Vitro Translation			N/A		N/A						
Osmolality			N/A	N/A	N/A			-			
Osmoranty			IV/A	IN/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						
					-			1			
N/A = not required per the stal	bility protocol; B, M, E = beginning, n	iiddle, end; kDa = kiloo	dalton; RT = retention	time; RRT = relative	retention time;						
*Sample handling issue with 9	opurity samples. An additional sample	was pulled at 50 days	on 21Mar20 for %pur	rity by RP-HPLC anal	ysis. The data were us	ed for 1M results	<b>3.</b>				
	CO.		_								
Confidential	× 0										Page
Connachiai	-0,										r ago .
	~⊘,										
	. M										
	documentca										
	. 00										
	20										
. 0											

mRNA-1273

Stability Results for Development mRNA-1273 Drug Product, DHM-47519 (0.10 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition) Table 2:

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	White to off-white dispersion, essentially	White to off-white dispersion, essentially		White to off-white dispersion, essentially	of Co		
	product-related particulates	free of particulates	free of particulates	free of particulates	free of particulates			
dentification	Sequence matches description	Conforms	N/A	N/A	N/A	10 dv		
by RT/ Sanger Sequencing	Sequence materies description	Contornis	1071	1071	1021	and		
RNA content			N/A			. 7 2 .		
by AEX-HPLC			·					
Purity by RP-HPLC	nain peak area					<del></del>		
Product-related impurities	Report % Impurity group 1					4 4		
by RP-HPLC	Report % Impurity group 2					` , <del>()</del> '	+	-
% RNA encapsulation	Report % Impurity group 3					A Commence of the Commence of		
by RiboGreen (Fluorescence)								
Lipid identification by UPLC-					011.0	<i>*</i>		
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		Comonny	1011	-0	Comonia	I de la constantina della cons		di
SM102			N/A	7				
Cholesterol			N/A					
DSPC			N/A					
PEG2000-DMG			N/A					
		RRT % Area		RRT % Area	RRT % Area			
			Ø,					
	Report RRT and % Area							
Lipid impurities	for individual impurities		N/A					
y UPLC-CAD	_		N/A O			1		
	Report % Area of Total Impurities	Total	V.O. 11	Total	Total			
Mean particle size								
by Dynamic light scattering								
Polydispersity	Report result							
by Dynamic light scattering	Report fesuit							
Н			N/A					
n Vitro Translation			N/A					
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			
Bioburden	lity protocol; nd; kDa = kilodalton; RT = retention tir		IVA	IVA	IV/A			

mRNA-1273

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

	Acceptance Criteria	0	1 month	2 month	3 month	4 month	5 month
	White to off-white dispersion. May	White to off-white	White to off-white				
Appearance	contain visible, white or translucent	dispersion, essentially	dispersion, essentiall				
	product-related particulates	free of particulates	free of particulates	free of particulates	free of particulates	free of particulates	free of particulates
Identification	Sequence matches description	Conforms	N/A	N/A	N/A	N/A	N/A
by RT/ Sanger Sequencing	Sequence materies description	Comorms	N/A	IVA	IVA	A WAY	IVA
RNA content			N/A			N/A	N/A
by AEX-HPLC			14/21			100	14/21
Purity by RP-HPLC	main peak area						
	Report % Impurity group 1						
Product related impurities	Report % Impurity group 2						
by RP-HPLC	Report % Impurity group 3						
% RNA encapsulation	resport // Impany group 5						
by RiboGreen (Fluorescence)							
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				10, 60, 90			
SM102			N/A			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
		RRT % Area	0 20	RRT N/A	RRT % Area		
			Taria in a				
	Report RRT and % Area		1/1/1/				
Lipid impurities	for individual impurities		N/A			N/A	N/A
by UPLC-CAD			12 -11:				
			VO. *10.				
	Report % Area of Total Impurities	Total	4, 18,	Total	Total		
Mean particle size							
by Dynamic light scattering							
Polydispersity	Report result						
by Dynamic light scattering	Report result						
pH			N/A			N/A	N/A
In Vitro Translation			N/A			N/A	N/A
Osmolality			N/A	N/A	N/A	N/A	N/A
Particulate matter			N/A	N/A	N/A	N/A	N/A
1 at ticulate matter							
Bacterial endotoxin			N/A	N/A	N/A	N/A	N/A
Richurden			N/A	N/A	N/A	N/A	NI/A
Biodurach		,,,	11/12	IVA	IVA	IVA	10/21
Bioburden  /A = not required per the stability pro	tocol;	(A),	N/A	N/A	N/A	N/A	N/A

mRNA-1273

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

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
	White to off-white dispersion. May		White to off-white	White to off-white	White to off-white			3 (7)			
Appearance	contain visible, white or translucent product-related particulates	dispersion, essentially free of particulates	dispersion, essentially free of particulates	dispersion, essentially free of particulates			.0	TAP			
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A		620	W.			
RNA content by AEX-HPLC			N/A		N/A		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \				
Purity by RP-HPLC	main peak area						10 CO				
• •	Report % Impurity group 1		+				39			<u> </u>	-
Product related impurities	Report % Impurity group 1		•			5(0)	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \				
by RP-HPLC	Report % Impurity group 3				i i	_m	1				
% RNA encapsulation						W	/				
by RiboGreen (Fluorescence)						0, 0					1
Lipid identification by UPLC						0, 0	4	ı			
SM102	Matches RT of standard	Conforms	N/A	Солбогтѕ	Conforms	<i>√0</i> ) —				<del> </del>	
Cholesterol DSPC	Matches RT of standard	Conforms Conforms	N/A N/A	Conforms Conforms	Conforms Conforms	$\omega$	-			-	+
PEG2000-DMG	Matches RT of standard Matches RT of standard	Conforms	N/A N/A	Conforms	Conforms	V					-
Lipid content by UPLC-CAD		Comonis	N/A	Comornis	Comonis		1			1	
SM102			N/A		() OV						
Cholesterol			N/A								
DSPC			N/A								
PEG2000-DMG			N/A								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities		N/A		No impurities detected						
Maria acadala ata	Report % Area of Total Impurities	Total		Total							1
Mean particle size by Dynamic light scattering											
Polydispersity										+	1
by Dynamic light scattering	Report result										
pH In Vitro Translation			N/A N/A		N/A						-
Osmolality			N/A	N/A	N/A		-			+	1
					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						
I/A = not required per the stable, M, E = beginning, middle, expanded by the sample handling issue with %		time; RRT = relative was pulled at 50 day	retention time; s on 21Mar20 for %	purity by RP-HPLC a	malysis. The data wer	re used for 1M re	esults.			I .	
Confidential	nd; kDa = kilodalton; RT = refention purity samples. An additional sample										Pa
36	40cn										

mRNA-1273

Stability Results for Development mRNA-1273 Drug Product, DHM-47516 (0.5 mg/mL) Stored Between -15°C to -25°C (Intended Storage Condition) Table 5:

White to off-white tipersion, essentially free of particulates  Conforms  Conforms  Conforms  Conforms  Conforms  Conforms  Conforms  RRT   % Area	N/A	White to off-white dispersion, essentially free of particulates  N/A  Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms	White to off-white dispersion, essentially free of particulates  N/A  Conforms  Conforms  Conforms  Conforms  Conforms  Conforms	Treatied			
conforms Conforms Conforms Conforms Conforms Conforms Conforms RRT   % Area	N/A	Conforms Conforms Conforms Conforms Conforms Conforms	free of particulates N/A  Conforms Conforms Conforms Conforms	A 7			
Conforms Conforms Conforms Conforms Conforms RRT   % Area	N/A	Conforms Conforms Conforms Conforms RRT % Area	N/A  Conforms Conforms Conforms Conforms	A 7			
Conforms Conforms Conforms Conforms RRT   % Area	N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/A	Conforms Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms	A 7			
Conforms Conforms Conforms Conforms RRT   % Area	N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/A	Conforms Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms	and and of	2		
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms	A FEBRUARY			
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms	And July 1			
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms				
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms				
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms				
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms				
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms	Ď			
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms				
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms Conforms Conforms				
Conforms Conforms Conforms RRT   % Area	N/A N/A N/A N/A N/A N/A N/A N/A N/A	Conforms Conforms Conforms RRT % Area	Conforms Conforms				
Conforms Conforms  RRT   % Area	N/A N/A N/A N/A N/A N/A	Conforms Conforms RRT % Area	Conforms Conforms				
RRT   % Area	N/A N/A N/A N/A N/A N/A	Conforms  RRT % Area	Conforms				
RRT   % Area	N/A N/A N/A N/A	RRT   % Area	- \				
	N/A N/A N/A		O// <sub>k</sub>				
	N/A N/A N/A						
	N/A N/A						
	N/A						
			S.C. Carlotte		1		
Total	\2\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		No impurities detected				
3 Total	14,1136	Total					
	N/A	N/A					
	N/A	N/A					
	N/A	N/A	N/A				
	N/A	N/A	N/A				
ime	; RRT = relative reter	N/A N/A N/A N/A N/A N/A R/A R/A R/T = relative retention time;	N/A	N/A	N/A	N/A	N/A

mRNA-1273

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

Acceptance Criteria	0	1 month	2 month	3 month	4 month	5 month
White to off-white dispersion. May	White to off-white	White to off-white	White to off-white	White to off-white	White to off-white	White to off-white
contain visible, white or translucent	dispersion, essentially	dispersion, essentially	dispersion, essentially	dispersion, essentially	dispersion, essentially	dispersion, essentia
product-related particulates	free of particulates	free of particulates	free of particulates	free of particulates	free of particulates	free of particulate
Saguanca metahas description	Conforms	NI/A	N/A	NI/A	N/A	N/A
Sequence matches description	Comorms	IVA	IVA	IVA	IV/A	) IVA
		NI/A	0.4	0.4	NI/A	N/A
<u></u>		N/A	0.4	0.4	OVA	N/A
main peak area						
Report % Impurity group 1						
, , , , , , , , , , , , , , , , , , , ,						
AD				-0, -(,		
	Conforms	N/A	Conforms	Conforms	N/A	N/A
						N/A
						N/A
						N/A
Machines ICI of Standard	Comornia	14/11		Comorning	1471	14/21
		N/A	101.6		N/A	N/A
						N/A
						N/A
						N/A
	DDT 0/4 Area		DDT - 04 Area	DDT 0/ Aren	IVA	IVA
	KKI 70 Alea	0	AKI 70 Alea	KKI /0 Alea		
		255				
		7/0				
for individual impurities		N/A			N/A	N/A
		V.O. 1/1/				
		11 10				
		VA 40),				
Report % Area of Total Impurities	Total	0, 00	Total	Total		
Report 70 2 feet of Total Impariace	1000	( AV)	Total	1000		
Report result						
		N/A			N/A	N/A
						N/A
			N/A	NI/A		N/A
		N/A	N/A	N/A	N/A	N/A
		N/A	N/A	N/A	N/A	N/A
						N/A
		I N/A	N/A		N/A	
	product-related particulates  Sequence matches description  main peak area  Report % Impurity group 1  Report % Impurity group 2  Report % Impurity group 3	Product-related particulates  Sequence matches description  Conforms  Table 1  Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Matches RT of standard Conforms Matches RT of standard Matches RT of standard Conforms Conforms Matches RT of standard Matches RT of standard Conforms Matches RT of standard Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Total	product-related particulates  Sequence matches description  Conforms  N/A  Main peak area  Report % Impurity group 1  Report % Impurity group 2  Report % Impurity group 3  AD  Matches RT of standard  Matches RT of standard  Conforms  N/A  Matches RT of standard  Report RT and % Area  for individual impurities  Total	product-related particulates  Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Product-related particulates  Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	product-related particulates  Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/

mRNA-1273

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

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

Test	Reference Criteria Intended Storage -15°C to -25°C)	0	1 month	2 mouth	3 month	6 moath	9 month	12 moath	18 moath	24 mouth
Appearance	White to off-white dispersion. May contain visible, white or translucent product-related particulates	White to off-white dispersion, essentially free of particulates	10.500 S00.500 1	40,000						
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A					
RNA content by AEX-HPLC				N/A			A.)			
Purity by RP-HPLC	main peak area (a)					~'0'	VD)			
	Report % Impurity group 1			i e		7.7	dr			
Product related impurities	Report % Impurity group 2					337.7.3				
by RP-HPLC	Report % Impurity group 3					70 AX				
% RNA encapsulation	7 , 9 - 7					NY AV				
by RiboGreen (Fluorescence)						AN .				
Lipid identification by UPLC					1 04	7				
SM102	Matches RT of standard	Conforms			0 0	3				
Cholesterol	Matches RT of standard	Conforms	N/A	N/A	N/A					
DSPC	Matches RT of standard	Conforms	IN/A	IV/A	IVA					
PEG2000-DMG	Matches RT of standard	Conforms		70%	· CO / CO)					
Lipid content by UPLC-CAD				c),	JU ON	_				
SM102				0.10						
Cholesterol				N/A						
DSPC				N/A						
PEG2000-DMG				O. 7 ~						
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities  Report % Area of Total Impurities	RRT % Area	RRT % Area	lation NA	RRT % Area					
Mean particle size by DLS										
Polydispersity by DLS				37/						
pH			27/4	N/A	37/4					
Osmolality			N/A	N/A	N/A					
In Vitro Translation				N/A			1			
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 = kilodalfon; RT = retention time; RRT = relative retention time a = Applies to stability testing only. Release acceptance criteria for purity by RP-HPLC is ≥

mRNA-1273

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

	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	, F					
dentification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A	7,000		
NA content by AEX-HPLC				N/A		1		
Purity by RP-HPLC	main peak area(a)							
Dun divet melate d immunition	Report % Impurity group 1							
Product related impurities by RP-HPLC	Report % Impurity group 2 Report % Impurity group 3	-		-				
% RNA encapsulation by RiboGreen (Fluorescence)				_				
Lipid identification by UPLC-		_		-	10		1	
SM102	Matches RT of standard	Conforms		_(	), -(,			
Cholesterol	Matches RT of standard	Conforms		, , , , , , ,	(0)			
DSPC	Matches RT of standard	Conforms	N/A	N/A	N/A			
PEG2000-DMG	Matches RT of standard	Conforms	-	0 00	N		1	
Lipid content by UPLC-CAD	Matches K1 of standard	Comoins		3. ×10 10/		(PAC)	1	
SM102				W. W. W.				
Cholesterol				D. 182 V2			-	
				N/A				
DSPC				100 1				
PEG2000-DMG				10				
		RRT % Area	RRT % Area	7	RRT % Area			
				$\bigcirc$ $^{\setminus}$				
	D . DDW 10/ 4			/				
Lipid impurities	Report RRT and % Area							
by UPLC-CAD	for individual impurities		(3)	N/A				
by CI LC-CILD			70 1 30					
						<del></del>		
			- 1 2 - 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
	D 10/4 00 117 11	m . 1	( ) m + 1 ( )		T . 1			
	Report % Area of Total Impurities	Total	Total		Total			
Mean particle size hy DLS								
Polydispersity by DLS								
PΗ				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation				N/A				
			27/4		27/4			
Particulate matter			N/A	N/A	N/A			
Container content			N/A	N/A	N/A			
Bacterial endotoxin			N/A	N/A	N/A	and the second s		1000
Sterility	No Growth	No Growth	N/A	N/A	N/A			

mRNA-1273

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

Acceptance Criteria	0	1 month	2 month	76 days	3 month	4 month	6 month
White to off-white dispersion. May contain visible, white or translucent	White to off-white dispersion, essentially	White to off-white dispersion, essentially	White to off-white dispersion, essentially	White to off-white dispersion, essentially	White to off-white dispersion, essentially		
product-related particulates  Sequence matches description	free of particulates  Conforms	free of particulates N/A	free of particulates N/A	free of particulates N/A	free of particulates  N/A	į.	
					0 1		
			N/A	N/A	'		
Report % Impurity group 3				YO A			
			N/A	N/A			
)				1100 D.			
	Conforms			0, 0,			
			200	6, 0.			
Matches RT of standard	Conforms	N/A	N/A	N/A	N/A		
Matches RT of standard	Conforms		2: :0	000			
			-000 3/100/				
			102:00	`			
			NA OV	N/A			
			P. " VO." VO	14/11			
			177				
Report RRT and % Area for individual impurities		7 70	N/A	N/A			
Report % Area of Total Impurities	Total	Total			Total		
			N/A	N/A			
		♪ N/A	N/A	N/A	N/A		
			N/A	N/A			
		N/A	N/A	N/A	N/A		
		N/A	N/A	N/A	N/A		
		N/A	N/A	N/A	N/A		
No Growth	No Growth	N/A	N/A	N/A	N/A		
	Matches RT of standard  Report RRT and % Area for individual impurities  Report % Area of Total Impurities	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  RRT % Area  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  No Growth	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  RRT % Area  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  N/A  Matches RT of standard Conforms  Matches RT of standard Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  N/A  Matches RT of standard	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  Matches RT of standard Conforms  RRT % Area  RRT % Area	main peak area <sup>60</sup> Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  Matches RT of standard Conforms  Matches RT of standard Conforms  RRT % Area  RRT % Area  RRT % Area  Report RRT and % Area for individual impurities  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/

mRNA-1273

ModernaTX, Inc. 3.2.P.8.3 Stability Data

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

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	White to off-white dispersion, essentially	White to off-white dispersion, essentially	White to off-white dispersion, essentially
	product-related particulates	free of particulates	free of particulates	free of particulates
dentification	Sequence matches description	Conforms	N/A	N/A
y RT/ Sanger Sequencing	1			
RNA content by AEX-HPLC				
Purity by RP-HPLC	main peak area <sup>(a)</sup>			
roduct related impurities	Report % Impurity group 1			
roduct related impurities by RP-HPLC	Report % Impurity group 2			
ly Ki -III LC	Report % Impurity group 3			
% RNA encapsulation				
y RihoGreen (Fluorescence)				
Lipid identification by UPLC-CAD			76.	
SM102	Matches RT of standard	Conforms	1 0%, 1	0
Cholesterol	Matches RT of standard	Conforms		N/A
DSPC	Matches RT of standard	Conforms	WA.	N/A
PEG2000-DMG	Matches RT of standard	Conforms	Na in all	
ipid content by UPLC-CAD			107.80 VO/	
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
.ipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities			
	Report % Area of Total Impurities	Total X	Total	Total
Mean particle size by DLS				
Polydispersity hy DLS				
Н				
n Vitro Translation Da = kilodalton; RT = retention time; RF				
onfidential	RT = relative retention time se acceptance criteria for purity by RP-HP	8		

mRNA-1273

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

(Intended Storage -15°C to -25°C)	0	1 month	2 month	3 month	6 month	9 month	12 month	18 month	24 month
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		2 top			
Sequence matches description	Conforms	N/A	N/A	N/A		) A'			
			N/A			(0)			
main mast area(8)			IVA			(V)			
•				i	(X)	<u> </u>			
					<del>- 00, 42</del>				
					77				
respect 70 imparity group 5					$(\mathcal{S}^{-1})^{*}$				
					1.0				
CAD				, &	, 0				
Matches RT of standard	Conforms			20 0					
Matches RT of standard	Conforms	N/A	N/A	N/A O	<b>*</b>				
Matches RT of standard	Conforms	14/71	-O	WILL STATE					
Matches RT of standard	Conforms		. 70,	50 Kg/					
			- J) ~(	1 OK					
			0,70						
			N/A						
			21. 30- 4						
	RRT % Area	RRT % Area	00 (1)	RRT % Area					
Report RRT and % Area for individual impurities  Report % Area of Total Impurities	Total	Total	N/A	Total					
1		1/) 1/10							
		N/A		N/A					
		0	N/A						
		N/A	N/A	N/A					
		NI/A	N/A	NT/A					
No Growth	No Growth		N/A						
	main peak area <sup>(6)</sup> Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Matches RT of individual impurities	main peak area <sup>(6)</sup> Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  RRT	main peak area <sup>(a)</sup> Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Tonforms  Matches RT of standard Tonforms  N/A  RRT % Area  Report % Area of Total Impurities  Total  N/A  N/A  N/A  N/A  N/A	main peak area <sup>(a)</sup> Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard N/A  Matches RT of standard Conforms  N/A  RRT   % Area   RRT   % Area  Report RRT and % Area for individual impurities  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Sequence matches description  Conforms  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/

mRNA-1273

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

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	A 30					
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A	1000		
RNA content by AEX-HPLC				N/A				
Purity by RP-HPLC	main peak area <sup>(a)</sup>					35.		. 10
Product related impurities	Report % Impurity group 1							
by RP-HPLC	Report % Impurity group 2							
by RF-HFLC	Report % Impurity group 3							
% RNA encapsulation by RiboGreen (Fluorescence)								
Lipid identification by UPLC-C	CAD							
SM102	Matches RT of standard	Conforms			1. 01,			
Cholesterol	Matches RT of standard	Conforms	7	- A	77/1			
DSPC	Matches RT of standard	Conforms	N/A	N/A	N/A			
PEG2000-DMG	Matches RT of standard	Conforms	1	0,00	P			
Lipid content by UPLC-CAD				DO TIS NA ASSE	4			
SM102				OCI NA				
Cholesterol								
DSPC				O. IVA				
PEG2000-DMG								
		RRT % Area	RRT % Area	2 /70	RRT % Area			
Lipid impurities	Report RRT and % Area							
by UPLC-CAD	for individual impurities			N/A				
	Report % Area of Total Impurities	Total	Total		Total			
Mean particle size by DLS	report /0 / new or rotal impurities	1 3441	1 300x		1000			
Polydispersity hy DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation			1444	N/A	17/11			
Particulate matter			N/A	N/A	N/A			
Gt-i			27/4	37/4	NT/A			
Container content			N/A	N/A	N/A			
Bacterial endotoxin	No Count	N- 00-4	N/A	N/A	N/A			
Sterility	No Growth	No Growth	N/A	N/A	N/A		I .	

N/A = not required per the stability protocol; kDa = kilodalton;

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

Confidential

mRNA-1273

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

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						
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A	NA		
RNA content by AEX-HPLC				N/A	N/A ?			
Purity by RP-HPLC	nain peak area <sup>(a)</sup>							
B 1 4 14 15 55	Report % Impurity group 1							
Product related impurities	Report % Impurity group 2							
by RP-HPLC	Report % Impurity group 3					_		
% RNA encapsulation by RiboGreen (Fluorescence)				N/A	N/A			
Lipid identification by UPLC-CAD	)	-		_ (	1, 0	-		
SM102	Matches RT of standard	Conforms		, ,0,	1, 0,			
Cholesterol	Matches RT of standard	Conforms	N/A	TIA O	N/A	N/A		
DSPC	Matches RT of standard	Conforms	N/A	TVA	N/A	N/A		
PEG2000-DMG	Matches RT of standard	Conforms		S. 10 'U'	1			
Lipid content by UPLC-CAD	_		. (	25 S. OIL				
SM102				13 783				
Cholesterol				N/A	N/A			
DSPC				14/67	17/74			
PEG2000-DMG				10				
		RRT % Area	RRT % Area			RRT % Area		
				O'				
Lipid impurities	Report RRT and % Area			27/4	37/4			
by UPLC-CAD	for individual impurities			N/A	N/A			
•			į					
		0.	3 - Q.Y.					
	Report % Area of Total Impurities	Total	Total Total			Total		
Mean particle size by DLS								
Polydispersity by DLS								
pH				N/A	N/A			
Osmolality			N/A	N/A	N/A	N/A		
In Vitro Translation				N/A	N/A			
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 ≥

mRNA-1273

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

Appearance		0	24 hours	72 hours
••	White to off-white dispersion. May contain visible, white or translucent product-related	White to off-white dispersion, essentially	White to off-white dispersion, essentially	White to off-white dispersion, essentially
Identification	particulates  Sequence matches description	free of particulates  Conforms	free of particulates N/A	free of particulates N/A
by RT/ Sanger Sequencing	sequence manetaes description	Comoning	1411	. 775
RNA content by AEX-HPLC				
Purity by RP-HPLC	main peak area <sup>(a)</sup>			
D. 4. 4. 1.4. 1	Report % Impurity group 1			
Product related impurities by RP-HPLC	Report % Impurity group 2			
by Kr-HFLC	Report % Impurity group 3			
% RNA encapsulation by RiboGreen (Fluorescence)				
Lipid identification by UPLC-0	CAD		-0.	
SM102	Matches RT of standard	Conforms	. 204	0,
Cholesterol	Matches RT of standard	Conforms	1 00 000	
DSPC	Matches RT of standard	Conforms	NVA OF OO	N/A
PEG2000-DMG	Matches RT of standard	Conforms	→ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	
Lipid content by UPLC-CAD	THE PARTY OF PRINCIPAL OF PRINC	Comorina	10/ 63/ 0/	
SM102			10 10 10	
Cholesterol				
DSPC				
PEG2000-DMG				
	_	RRT % Area Q	RRT % Area	RRT % Area
		7071100	/071100	7071100
Lipid impurities	Report RRT and % Area			
by UPLC-CAD	for individual impurities			
by of be-end				
	Report % Area of Total Impurities	Total	Total	Total
Mean particle size by DLS	Report 78 Area of Total Impurities	Total	Total	10141
Polydispersity by DLS	-			
pH				
In Vitro Translation				
I/A = not required per the stabili Da = kilodalton; RT = retention = Applies to stability testing on	time; RRT = relative retention time tly. Release acceptance criteria for purity by RP-	HPLC is ≧		
	ity protocol; time; RRT = relative retention time tly. Release acceptance criteria for purity by RP-	× ·		
Confidential	Therit co.			

mRNA-1273

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

Intended Storage -15°C to -25°C)	0	1 month	2 month	3 month	6 month	9 month	12 month	18 month	24 month
White to off-white dispersion. May		White to off-white	White to off-white	White to off-white		(0)			
contain visible, white or translucent	dispersion, essentially	dispersion, essentially	dispersion, essentially	dispersion, essentially		65.45			
product-related particulates	free of particulates	free of particulates	free of particulates	free of particulates		7. A. CAN			
Sequence matches description	Conforms	N/A	N/A	N/A		(0.)			
			NT/A			<del>                                      </del>			
. 1 (9)			N/A		0	·0) '		+	
						2.0			
					- A * A	D,			
Report % Impurity group 2			-						
Report % Impurity group 3			_		$-\alpha^{y_{2}}A$				
					$O_{\lambda} = O_{\lambda}$				
AD	_			-()	-(1)	I I			
	Conforms			, 201	0				
				00,000					
Matches RT of standard	Conforms	N/A	N/A	N/A	1				
Matches RT of standard	Conforms		0,0	10-100					
			707	· C,O ,O)/.					
			1/1						
			N/A						
			Olan III.						
			Mr. Mr.						
	RRT % Area	RRT % Area	0 7 -	RRT   % Area					
			10,69,						
Donart BBT and 9/ Area			1111						
			NYA						
ioi individuai impairdes			IVA						
			NIO NI						
			10.						
Report % Area of Total Impurities	Total	Total	7.	Total					
			N/A						
		N/A		N/A					
			N/A						
		N/A	N/A	N/A					
No Growth	No Growth	N/A	N/A	N/A					
I	Matches RT of standard  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  No Growth ty protocol;	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Total  Report % Area of Total Impurities  Report % Area of Total Impurities  No Growth	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  AD  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  RRT % Area  RRT % Area  RRT % Area  Report % Area of Total Impurities  Report % Area of Total Impurities  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  ND  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  N/A  RRT % Area  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  Matches RT of standard Conforms  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	main peak area (*)  Report % Impurity group 1  Report % Impurity group 2  Report % Impurity group 3  **Matches RT of standard	nain peak area (*)  Report % Impurity group 1  Report % Impurity group 2  Report % Impurity group 3  Matches RT of standard Conforms  N/A  RRT % Area  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Report % Area of Total Impurities  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Report % Impurity group 1 Report % Impurity group 2 Report % Impurity group 3  Authors RT of standard Conforms Matches RT of standard Conforms  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Report % Area of Total Impurities  Report % Area of Total Impurities  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Report ½ Impurity group 2 Report ½ Impurity group 2 Report ½ Impurity group 2 Report ½ Impurity group 3  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Matches RT of standard Conforms  Report RRT and % Area for individual impurities  Report % Area of Total Impurities  Report % Area of Total Impurities  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/

mRNA-1273

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

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	A 63		ale in de indécide de la companya de			
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A	4,00		
RNA content by AEX-HPLC				N/A		A *		
Purity by RP-HPLC	main peak area <sup>(a)</sup>					72,		
	Report % Impurity group 1					39		
Product related impurities	Report % Impurity group 2					-		
by RP-HPLC	Report % Impurity group 3							
% RNA encapsulation	Inspect to Emparity group o							
by RiboGreen (Fluorescence)								
Lipid identification by UPLC-0	CAD				110			
SM102	Matches RT of standard	Conforms			10, 20,			
Cholesterol	Matches RT of standard	Conforms	37/4	27/8	S . O .			
DSPC	Matches RT of standard	Conforms	N/A	N/A	N/A			
PEG2000-DMG	Matches RT of standard	Conforms			0			
Lipid content by UPLC-CAD				000000	/			
SM102				104.80 101				
Cholesterol				The Clark				
DSPC				O IN/A				
PEG2000-DMG								
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT % Area	RRT % Area	N/A	RRT % Area			
	Report % Area of Total Impurities	Total	Total		Total	-		
Mean particle size by DLS	The state of Long Inputition	_ 5001						
Polydispersity hy DLS								
pH				N/A				
Osmolality			N/A	N/A	N/A			
In Vitro Translation				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	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 ≥

mRNA-1273

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

	Acceptance Criteria	0	1 month	2 month	76 days	3 month	4 month	6 month
	White to off-white dispersion. May	White to off-white						
Appearance	contain visible, white or translucent	dispersion, essentially						
	product-related particulates	free of particulates	free of particulates	free of particulates	free of particulates	free of particulates		
dentification	Sequence matches description	Conforms	N/A	N/A	N/A	N/AO		
by RT/ Sanger Sequencing	Sequence matches description	Comornis	N/A			N/A)		
RNA content by AEX-HPLC				N/A	N/A			
Purity by RP-HPLC	main peak area <sup>(8)</sup>							
unty by Rt -III EC				-				
Product related impurities	Report % Impurity group 1							
by RP-HPLC	Report % Impurity group 2							
y KI-III LE	Report % Impurity group 3							
% RNA encapsulation				N/A	NIA			
by RiboGreen (Fluorescence)				IVA	N/A			
Lipid identification by UPLC-CAD	)				0, 0			
SM102	Matches RT of standard	Conforms		~	D4' O,			
Cholesterol	Matches RT of standard	Conforms	1	- N	27/4	37/4		
DSPC	Matches RT of standard	Conforms	N/A	ON/A	N/A	N/A		
PEG2000-DMG	Matches RT of standard	Conforms	1	S. 70, U	2			
Lipid content by UPLC-CAD		1		0/2 - W/ 0/				
SM102				(A. 180 - 180).				
Cholesterol				0/1"On				
DSPC				N/A	N/A			
PEG2000-DMG				111 10				
1 Ed2000-Birid		RRT % Area	RRT % Area	2. 42°		RRT % Area		
		7071108	Kiti // 170 Mica			Idei 70 Mica		
				.0 \				
Lipid impurities	Report RRT and % Area							
by UPLC-CAD	for individual impurities			N/A	N/A			
by OFIC-CAD								
	Donat Of Assault Institution	T-4-1	77.4.1			T-4-1		
	Report % Area of Total Impurities	Total	Total			Total		
Mean particle size by DLS								
Polydispersity by DLS				27/4	27/4			
oH			27/4	N/A	N/A	27/4		
Osmolality			N/A	N/A	N/A	N/A		
n Vitro Translation				N/A	N/A			
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		

mRNA-1273

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

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	Sequence matches description	Conforms	N/A	N/A
by RT/ Sanger Sequencing	Bequence materies description	Contorns	1971	14/1
RNA content by AEX-HPLC				
Purity by RP-HPLC	nain peak area			
Product related impurities	Report % Impurity group 1			
by RP-HPLC	Report % Impurity group 2			
•	Report % Impurity group 3			
% RNA encapsulation				
by RiboGreen (Fluorescence) Lipid identification by UPLC-				
SM102	Matches RT of standard	Conforms	100	0,
Cholesterol	Matches RT of standard	Conforms		
DSPC	Matches RT of standard	Conforms	N/A SULLING TO THE SECOND TO T	) N/A
PEG2000-DMG	Matches RT of standard	Conforms		
Lipid content by UPLC-CAD	Transactor Ita di Dellatata	Comornia	0/ 0/ 0//	
SM102			10 .0.	
Cholesterol				
DSPC				
PEG2000-DMG	-			
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities		NO.	
	Report % Area of Total Impurities	Total	Total	Total
Mean particle size by DLS				
Polydispersity by DLS				
pH In Vitor Terroletian				
In Vitro Translation	1 time; RRT = relative retention time			
	n time; RRT = relative retention time nly. Release acceptance criteria for purity	coledese de la colede		
Confidential	'Y'CS.			

mRNA-1273

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

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
	White to off-white dispersion. May		White to off-white	White to off-white			10,7			
Appearance	contain visible, white or translucent						AT 45			
	product-related particulates	free of particulates					14 Ch			
Identification	Sequence matches description	Conforms	N/A	N/A						
by RT/ Sanger Sequencing	<u> </u>	Comornis	N/A				733 LV Y			
RNA content by AEX-HPLC				N/A		λ.				
Purity by RP-HPLC	nain peak area <sup>(a)</sup>					~(\)~	ANY			
	Report % Impurity group 1						<b>*</b>			
Product related impurities	Report % Impurity group 2									
by RP-HPLC	Report % Impurity group 3					XY X				
% RNA encapsulation	1 1 78 1					20 21				
by RiboGreen (Fluorescence)						Y				
Lipid identification by UPLC					70	. 7/				
SM102	Matches RT of standard	Conforms			A OX	L U				
Cholesterol	Matches RT of standard	Conforms	NT/A	N/A	A A C					1011
DSPC	Matches RT of standard	Conforms	N/A	N/A	200	1				
PEG2000-DMG	Matches RT of standard	Conforms			- 10 M					
Lipid content by UPLC-CAD				407	CO 10/1					
SM102				-111 -1	SY AV					
Cholesterol				NA VO	1 NU				9.00	
DSPC				NA HI	Α					
PEG2000-DMG				all all a						
		RRT % Area	RRT % Area	0, 7,0-7	<b>V</b>					
	Report RRT and % Area			0,0						
Lipid impurities	for individual impurities			NT/A						
by UPLC-CAD	101 marviduai impurities			N/A						
				7.00						
	Report % Area of Total Impurities	Total	Total							
Mean particle size by DLS										
Polydispersity by DLS										
pH				N/A						
Osmolality			N/A	N/A						
In Vitro Translation			- 1/	N/A						
Particulate matter			N/A	N/A						
			~~							
Container content			N/A	N/A						
Bacterial endotoxin			N/A	N/A		1000				
Sterility	No Growth	No Growth	N/A	N/A						
kDa = kilodalton; RT = retent a = Applies to stability testing Confidential	ion time; RRT = relative retention time only. Release acceptance criteria for p	e county by RP-HPLC is ≥								Pag

mRNA-1273

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

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		£ 63		
Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A		3,00h		
RNA content by AEX-HPLC				N/A	9			
Purity by RP-HPLC	main peak area(a)				Ò			
Product related impurities	Report % Impurity group 1				<u>^```</u>	U.		
by RP-HPLC	Report % Impurity group 2							
	Report % Impurity group 3				(2) (N)			
% RNA encapsulation					AN A N			
by RiboGreen (Fluorescence)								
Lipid identification by UPLC-0 SM102	Matches RT of standard	Conforms						
Cholesterol	Matches RT of standard	Conforms			Dx O,			-
DSPC	Matches RT of standard	Conforms	N/A	N/A	100		-	
PEG2000-DMG	Matches RT of standard	Conforms		6 00	$\leftrightarrow$		+	
Lipid content by UPLC-CAD	Wateries KT of standard	Comornis		10 10 10	7		- L	
SM102				10, 3, 01				
Cholesterol				10 115 013				
DSPC				N/A				
PEG2000-DMG				XXII O				
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities	RRT % Area	RRT % Area	N/A				
	Report % Area of Total Impurities	Total	Total					
Mean particle size by DLS								
Polydispersity by DLS				NT/A				
pH Osmolality			N/A)	N/A N/A				
In Vitro Translation			(A) AVA()	N/A N/A				
Particulate matter			N/A	N/A				
			70.					
Container content			N/A N/A	N/A				
	No Growth	No Growth	N/A N/A	N/A N/A				
Bacterial endotoxin Sterility			IN/A	IN/A				

mRNA-1273

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

Test	Acceptance Criteria	0	1 month	2 month	76 days	3 month	4 month	6 month
	White to off-white dispersion. May	White to off-white	White to off-white	White to off-white	White to off-white			
Appearance	contain visible, white or translucent	dispersion, essentially	dispersion, essentially	dispersion, essentially	dispersion, essentially	XV _		
11	product-related particulates	free of particulates	free of particulates	free of particulates	free of particulates	おしょう		
Identification		_		_		14 KV		
by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A	N/A	AN AY		
RNA content by AEX-HPLC				N/A	N/A	03 L T		
-	(1)			1012	1011	C) . "		
Purity by RP-HPLC	main peak area <sup>(n)</sup>					(0)		
	Report % Impurity group 1							
Product related impurities	Report % Impurity group 2					U		
by RP-HPLC	Report % Impurity group 3					1		
% RNA encapsulation	Report 70 Impurity group 5				V/, \			
				N/A	ON/A			
by RiboGreen (Fluorescence)					10			
Lipid identification by UPLC-CAI					6, 4			
SM102	Matches RT of standard	Conforms	1	,	5 / O.			
Cholesterol	Matches RT of standard	Conforms	N/A	N/A				
DSPC	Matches RT of standard	Conforms	] IVA	JVA (	N/A			
PEG2000-DMG	Matches RT of standard	Conforms		3. ×10 10	2			
ipid content by UPLC-CAD				06 30 01				
SM102				C 1/2 - 1/2				
Cholesterol				, 41, On				
DSPC	-			N/A	N/A			
PEG2000-DMG	-			(1)				
FEG2000-DMG		RRT % Area	RRT % Area	1				
		KR1 % Alea	RKI 76 Alea					
			-	$C^{1}$				
Lipid impurities	Report RRT and % Area			,				
by UPLC-CAD	for individual impurities			N/A	N/A			
by GI DC CIED								
	Report % Area of Total Impurities	Total	Total	Ī				
Mean particle size by DLS								
Polydispersity by DLS								
oH				N/A	N/A			
Osmolality	-		N/A	N/A	N/A			
			N/A					
In Vitro Translation	_			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	No Growth		2714					DESCRIPTION OF THE PROPERTY OF
	No Crrowin	No Growth	N/A	N/A	N/A			

mRNA-1273

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

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	White to off-white dispersion, essentially	White to off-white dispersion, essentially	White to off-white dispersion, essentially
dentification	product-related particulates	free of particulates	free of particulates	free of particulates
by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A
RNA content by AEX-HPLC				1/7
Purity by RP-HPLC	main peak area			
unity by KI-III EC				
Product related impurities	Report % Impurity group 1 Report % Impurity group 2			
y RP-HPLC	Report % Impurity group 2  Report % Impurity group 3			
% RNA encapsulation by RiboGreen (Fluorescence)				
Lipid identification by UPLC-				0. (
SM102	Matches RT of standard	Conforms		'Ox' O,
Cholesterol	Matches RT of standard	Conforms		
DSPC	Matches RT of standard	Conforms		N/A
PEG2000-DMG	Matches RT of standard	Conforms		27
Lipid content by UPLC-CAD	THEOLOGICA OF SMIRARE	Comornia	W 60.00	/ ~
SM102				
Cholesterol				
DSPC				
PEG2000-DMG				
		RRT %Area	RRT %Area	RRT %Area
Lipid impurities by UPLC-CAD	Report RRT and % Area for individual impurities			
	Report % Area of Total Impurities	Total	Total	Total
Mean particle size by DLS				
Polydispersity by DLS				
.TT				
n Vitro Translation				
= Applies to stability testing or	n time; RRT = relative retention time nly. Release acceptance criteria for purity	by RP-HPLC is a second of the control of the contro		

mRNA-1273

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

White to off-white lally dispersion, essentially dispersion, essentially ties free of particulates N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/A	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
rea RRT % Area RRT % Area  Total Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/		White to off-white dispersion. May	White to off-white					(0)			
N/A N/A  N/A N/A N/A  N/A N/A N/A  N/A N/A N/A  N/A N/A N	Appearance							or no			
N/A N/A  Total Total  Total N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/A	114:64:	product-related particulates	free of particulates	free of particulates	free of particulates			-3			
rea RRT % Area RRT % Area  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Identification by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A	N/A			(C) (V)			
rea RRT % Area RRT % Area  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	RNA content by AEX-HPLC						X				
rea RRT % Area RRT % Area  Total Total  N/A N/A	Purity by RP-HPLC	main peak area <sup>(a)</sup>					~~	.(0)			
rea RRT % Area RRT % Area  Total Total  N/A N/A		Report % Impurity group 1					0				
rea RRT % Area RRT % Area  Total Total  N/A N/A	Product related impurities	Report % Impurity group 2					A 70				
rea RRT % Area RRT % Area  Total Total  N/A N/A	by RP-HPLC	Report % Impurity group 3					W X				
rea RRT % Area RRT % Area  Total Total  N/A N/A	% RNA encapsulation						70° X\				
rea RRT % Area RRT % Area  Total Total  N/A N/A	by RiboGreen (Fluorescence)					3	$\vee$ $\vee$				
rea RRT % Area RRT % Area  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Lipid identification by UPLC-					20	, (()				
rea RRT % Area RRT % Area  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	SM102	Matches RT of standard	Conforms			_xax	L Y				
rea RRT % Area RRT % Area  Total  Total  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	Cholesterol	Matches RT of standard	Conforms	N/A	N/A	6) - C - C					
Total	DSPC	Matches RT of standard	Conforms		-7	$\leftarrow : O \rightarrow O$					
Total	PEG2000-DMG Lipid content by UPLC-CAD	Matches RT of standard	Conforms			2'0' O\\				1	
Total	SMI02				.0`	10 V					
Total	Cholesterol					V 10					
Total	DSPC										
Total	PEG2000-DMG										
N/A N/A			RRT % Area	RRT % Area	RRT % Area						
N/A N/A		Report RRT and % Area									
N/A N/A	Lipid impurities	for individual impurities									
N/A N/A	by UPLC-CAD	Tor marvadar impartaes									
N/A N/A					- 11						
N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A	Maria I DIG	Report % Area of Total Impurities	Total	Total	Total						
N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A	Mean particle size by DLS Polydispersity by DLS							100			
N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A	pH										
N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A  N/A N/A				NJ/A	N/A						
N/A N/A N/A N/A N/A N/A N/A N/A N/A				11112	1411						
N/A N/A N/A N/A N/A N/A N/A N/A N/A	D-1'-1			0 (8)	37/4						
N/A N/A N/A N/A N/A	Particulate matter										
N/A N/A											
	Sterility	No Growth	No growth	N/A	N/A						
	Osmolality In Vitro Translation Particulate matter Container content Bacterial endotoxin Sterility N/A = not required per the stal	No Growth bility protocol; on time; RRT = relative retention tim only. Release acceptance criteria for p	No growth  c c c c c c c c c c c c c c c c c c	N/A N/A N/A N/A	N/A N/A N/A						
	onfidential	aenit .									Pag
Pag	٠.۵	90chu.									
Рад	Kly										

mRNA-1273

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 Table 24:

Test	Acceptance Criteria	0	1 month	2 month	11 Weeks	3month
	White to off-white dispersion, May	White to off-white	White to off-white			13.0
Appearance	contain visible, white or translucent	dispersion, essentially	dispersion, essentially			0.T n 2
- pp - man-	product-related particulates	free of particulates	free of particulates			7,70
Identification						V1 1/2
by RT/ Sanger Sequencing	Sequence matches description	Conforms	N/A		. 10	A
RNA content by AEX-HPLC			N/A		70	(A)
Purity by RP-HPLC	main peak area <sup>(a)</sup>				AN .	O"
1 41107 07 14 111 20	Report % Impurity group 1				A 20	
Product related impurities			-			
by RP-HPLC	Report % Impurity group 2				- XX	
0/ DNIA	Report % Impurity group 3					
% RNA encapsulation			N/A		777 . N	
by RiboGreen (Fluorescence)					$\circ$	
Lipid identification by UPLC-C			T	eranomana kantan da kantan da ka	kerana uran dan dan dan dan dan dan dan dan dan d	
SM102	Matches RT of standard	Conforms	-		7	
Cholesterol	Matches RT of standard	Conforms	N/A			
DSPC	Matches RT of standard	Conforms		O W _O		
PEG2000-DMG	Matches RT of standard	Conforms				
Lipid content by UPLC-CAD				(0.10 Va)		
SM102						
Cholesterol			NY/A			
DSPC			N/A			
PEG2000-DMG			~(1)	V <sub>2</sub> Z		
		RRT % Area	(O, Y			
		701200		<b>∮</b> ,∪\		
Lipid impurities	Report RRT and % Area			(KZ		
hy UPLC-CAD	for individual impurities		N/A			
ny OFIC-CAD			1/2 1/2			
	D 10/1 00 17 1/	m · i	\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\			
	Report % Area of Total Impurities	Total	4, 4,	Access to the second se		
Mean particle size by DLS						
Polydispersity by DLS			A1 201			
pH			O' N/A			
Osmolality			N/A			
In Vitro Translation			N/A			
Nontinulate met-			NII			
Particulate matter			N/A			
Container content			N/A			
Bacterial endotoxin			N/A			
Sterility						
	No Growth	No growth	N/A			

mRNA-1273

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

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
	White to off-white dispersion. May	White to off-white	White to off-white	White to off-white						
Appearance	contain visible, white or translucent	dispersion, essentially	dispersion, essentially	dispersion, essentially			at 40			
	product-related particulates	free of particulates	free of particulates	free of particulates			V V V			
Identification	Sequence matches description	Conforms	N/A	N/A			W 102			
by RT/ Sanger Sequencing		Comornis	IVA	IVA.			λ <b>`</b> \ '			
RNA content by AEX-HPLC						الم ا	A3.3			
Purity by RP-HPLC	main peak area(a)					100	W			
	Report % Impurity group 1					100	•			
Product related impurities	Report % Impurity group 2					A 70	•			
by RP-HPLC	Report % Impurity group 3					WY.K				
% RNA encapsulation	respect to impainly group to					10° 41				
by RiboGreen (Fluorescence)						V 'V'				
Lipid identification by UPLC					Ö.				I.	
SM102	Matches RT of standard	Conforms				0				
Cholesterol	Matches RT of standard	Conforms			33 207	A				
DSPC	Matches RT of standard	Conforms	N/A	N/A	$\Theta = A \cap A$	<b>.</b>				
PEG2000-DMG	Matches RT of standard	Conforms		20						
Lipid content by UPLC-CAD		Сощонна		- 6	~!&\\\ O\\\				l-	
SMI02					79 13					
Cholesterol	-									
DSPC			N/A		**	+	-			
PEG2000-DMG				-						
FEG2000-DMG	<u> </u>	RRT % Area		RRT % Area		<del>                                     </del>				
		KKI 70 Alea		KKI 70 Alça						
Lipid impurities	Report RRT and % Area									
by UPLC-CAD	for individual impurities		N/A							
by OPIC-CAD										
	Description of the control of the co	Tree-1		maiste						
M	Report % Area of Total Impurities	Total	70	Total		-				
Mean particle size by DLS										
Polydispersity by DLS						1				
pH	_		1 Day 2 4	27/4						
Osmolality			X N/A	N/A						
In Vitro Translation	_		- ml	27/4		-				
Particulate matter			N/A	N/A						
			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						
RDa = Knocaton; R1 = retent a = Applies to stability testing  Confidential	ion time; RRT = relative retention time only. Release acceptance criteria for r	s maily by RP-HPLC is ≥								Paį

mRNA-1273

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 Table 26:

	Acceptance Criteria	0	1 month	2 month	11 Weeks	3 month
by RT/ Sanger Sequencing	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			10,20
	Sequence matches description	Conforms	N/A		. જ	1,7,h
			N/A		-6-	783
Purity by RP-HPLC	main peak area(a)		AVIA	Spin Service Control	68 3	10000
	Report % Impurity group 1				へ ぶつ	
Product related impurities	Report % Impurity group 2				30 69	
hy RP-HPLC	Report % Impurity group 3				V2 V ,	
% RNA encapsulation by RiboGreen (Fluorescence)			N/A		30° N	
Lipid identification by UPLC-CAI	<u> </u>	-			( <del>)</del> ()	
SM102	Matches RT of standard	Conforms				
Cholesterol	Matches RT of standard	Conforms		77	Ο	
DSPC	Matches RT of standard	Conforms	N/A	A 101 Z		
PEG2000-DMG	Matches RT of standard	Conforms			<i>F</i>	
Lipid content by UPLC-CAD	Machies KT of Standard	Comoms				
SM102		<u> </u>				
Cholesterol			(	<del></del>		
DSPC			N/A	- 10 To		
PEG2000-DMG			- allo	/\ <sup>3</sup>		
I EGZ000-DIVIG		RRT % Area	<b>⊘</b> ` ∠	420		
		KKI 76 Alca		).( <sub>1</sub> )		
Lipid impurities hy UPLC-CAD	Report RRT and % Area for individual impurities	- -	N/A			
	Report % Area of Total Impurities	Total	Jos Hills			
Mean particle size by DLS	tepore 70 1 total or 1 otal milparietes	1000	. / / /			
Polydispersity hy DLS						
pH			O N/A			
Osmolality			N/A			
In Vitro Translation		-	N/A			
			N/A			
Particulate matter			N/A			
Container content			N/A			
Bacterial endotoxin			N/A			
Sterility	No Growth	No growth	N/A			
I/A = not required per the stability t		No growm	N/A			

# 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)					
Purity by RP-HPLC	main peak area				
	Report % area impurity group 1				
Product related impurities by RP-HPLC	Report % area impurity group 2				
•	Report % area impurity group 3				
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering	Report result				

**Table 28:** 

	/ Thaw Cycling Data for Between -60°C to -90°C			HM-47522 (0.10 m	g/mL) idilons in of
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)		,			
Purity by RP-HPLC	main peak area				
	Report % area impurity group 1				
Product related impurities by RP-HPLC	Report % area impurity group 2				
3,	Report % area impurity group 3				
Mean particle size by Dynamic light scattering					
Polydispersity by Dynamic light scattering	Report result				

**Table 29:** 

	e/ Thaw Cycling Data fo d Between -60°C to -90°C				ymL)girations there	mRN
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)						
Purity by RP-HPLC	main peak area					
	Report % area impurity group 1					
Product related impurities by RP-HPLC	Report % area impurity group 2					
,	Report % area impurity group 3					
Mean particle size by Dynamic light scattering						
Polydispersity by Dynamic light scattering	Report result					

Confidential

**Table 30:** 

ModernaTX, Inc. 3.2.P.8.3 Stability Data					g/mL), righton's there	mRN
Table 30: Freez Store	e/ Thaw Cycling Data fo d Between -60°C to -90°	or mRNA-1273 Dr C and Thawed to	rug Product, Lot D 2°C to 8°C	HM-47518 (0.5 mg	y/mL) <sub>nitall</sub>	1
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)						
Purity by RP-HPLC	main peak area					
	Report % area impurity group 1					i
Product related impurities by RP-HPLC	Report % area impurity group 2					i
	Report % area impurity group 3					i
Mean particle size by Dynamic light scattering						
Polydispersity by Dynamic light scattering	Report result					

Confidential

#### 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	Initial*	RT	5°C	RT	5°C
Appearance	Report 1		White to o	f-white disp	ersion, essent	RT ially free of p	particulate
RNA content by AEX-HPLC		% Difference from Initial is					
Purity by RP-HPLC	main	peak area					
•	Report %Area for each	ch Impurity Group			%Area	F B	
	Impurity (	Froup 1					
Product related impurities by RP-HPLC	Impurity (	Froup 2					
oy la la Le	Impurity (	Froup 3					
	Total imp	urities					
In Vitro Translation							
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering		()					
Polydispersity by Dynamic light scattering	Report 1	esult 1107					
Lipid content by UPLC-CAD		3. 11/10	10				
SM-102		SU, 30 4					
Cholesterol		% Difference from					
DSPC		Initial is					
PEG2000-DMG		dio.					
	RR	<u>r</u>			%Area		
	RRT						
	RRT		ND			ND	
Lipid impurities	RRT		ND		ND		
(Report RRT and % Area)	RRT				-		
60, 30	RRT				_		
13.66	RRT				-		
100 /	RRT				-		
	RRT					-	
					N	/A	
Lipid impurities by UPLC-CAD (Report RRT and % Area)  pH Osmolality					N.I	r / A	

Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, **Table 32:** Lot 6006820001, 0.10 mg/mL, (Polycarbonate) Post 6 Hour Hold of Opened Multiple-Dose Vial

Acceptano	ce Criteria		Т=	= 8h	T =	24h
Initial	T8h and T24h	Initial*	RT	5°C	RT	5°C
Report	result	White to o	off-white disp	persion, essent	ially free of p	particulates
	% Difference from Initial is					
mai						
Report %Area for e	ach Impurity Group			%Area	5	0.
Impurity	Group 1					
Impurity	Group 2					
Impurity	Group 3					
Total in	purities					
Report	result					
		700	1			
	20.					
	% Difference from					
	Initial is					
	My Shir Mo					
R	RT. O.			%Area		
RRT						
RRT		ND				ND
RRT		ND	ND	ND		ND
RRI						
RRT						
RRT	,					
RRT						
RRT						
				N/	'A	
				N/	'A	
	Initial Report Report %Area for e Impurity Impurity Total in Report Report RRT RRT RRT RRT RRT	Report result  % Difference from Initial is main peak area  Report %Area for each Impurity Group Impurity Group 1 Impurity Group 2 Impurity Group 3 Total impurities  Report result  % Difference from Initial is  RRT  RRT  RRT  RRT  RRT  RRT  RRT  R	Initial  Report result  White to compare the second	Initial  Report result  Report result  White to off-white disponding in the properties of the properti	Initial T8h and T24h  Report result  White to off-white dispersion, essent  Initial is  main peak area  Report %Area for each Impurity Group  Impurity Group 1  Impurity Group 2  Impurity Group 3  Total impurities  Report result  % Difference from Initial is  RRT  RRT  RRT  RRT  RRT  RRT  RRT  R	Initial  Report result  Report result  White to off-white dispersion, essentially free of public and peak area  Report %Area for each Impurity Group  Impurity Group 1  Impurity Group 2  Impurity Group 3  Total impurities  Report result  **Difference from Initial is  Report result  **Note: The impurity Group is a second in the impurity Group is a second in the impurities in the impurities is a second in the impurities in the impurities is a second in the impurities

syringe material is expected

syringe material is expected

ND = not detected

N/A = not required per the stability protocol

RRT = relative retention time \* 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

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

Test	Acceptance	e Criteria	Initial*	T	= 8h	T =	= 24h
1681	Initial	T8h and T24h	IIIIIIai"	RT	5°C	essentially free of	5°C
Appearance	Repor	result	White to o	off-white dis	spersion, essen	tially free of	particulate
RNA content by AEX-HPLC		% Difference from Initial is					
Purity	mai	n peak area					
by RP-HPLC					0/ 1		0,
		ach Impurity Group			%Area	C	
Product related impurities	Impurity	Group 2					
by RP-HPLC		Group 3					
	Total in						
In Vitro Translation	1041111	ipurities					
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size by Dynamic light scattering							
Polydispersity	Danar	result					
by Dynamic light scattering	Report	. resurt	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	N		<u> </u>	
Lipid content by UPLC-CAD		Ø:	7 200	) '			
SM-102 Cholesterol		1000					
DSPC	_	% Difference from Initial is					
PEG2000-DMG		20. Mr. 70					
1202000 2.110	R	RT O			%Area		
	RRT	1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.					
	RRT		ND	ND			
Lipid impurities	RRT		ND	ND		ND	ND
by UPLC-CAD	RRI						
(Report RRT and % Area)	RRT						
	RRT						
*O	RRT						
-II 8 3	RRT						
pn S							
Osmolality  * Initial (T = 0) results were from The impact of syringe material sND = not detected N/A = not required per the stabilizer relative retention time					N	/A	

<sup>\*</sup> 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.

Clinical In-Use Compatibility Data for mRNA-1273 Drug Product **Table 34:** Lot 6006920001, 0.5 mg/mL, (Polycarbonate) **Unopened Multiple-Dose Vial** 

T4	Acceptar	Acceptance Criteria		T:	= 8h	T = 24h		
Test	Initial	T8h and T24h	Initial*	RT	5°C	RT	5°C	
Appearance	Repo	rt result	White to o	ff-white dis	persion, essen	tially free of	particulates	
RNA content by AEX-HPLC		% Difference from Initial is						
Purity by RP-HPLC	ma	nin peak area						
	Report %Area for each Impurity Group  Impurity Group 1				%Area	C	0	
Product related impurities by RP-HPLC	Impurit	y Group 2			RT 5°C RT  -white dispersion, essentially free of p  %Area			
0,14 14 16	Impurit	y Group 3						
	Total in	mpurities						
In Vitro Translation								
% RNA encapsulation by Fluorescence (RiboGreen)		_						
Mean particle size								
by Dynamic light scattering Polydispersity by Dynamic light scattering	Repo	rt result						
Lipid content by UPLC-CAD		_ 0	, , , , ,	1				
SM-102		.00.						
Cholesterol		% Difference from						
DSPC		Initial is						
PEG2000-DMG		Mis Vill Mo						
	F	ert O			%Area		•	
	RR	T						
Lipid impurities	RR	T						
by UPLC-CAD (Report RRT and % Area)	RR	Т						
(mpolitical min / vinon)	RR	ì						
	RR							
pH					N	I/A		
Osmolality					N	I/A		

<sup>\*</sup> 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

This document canno

Clinical In-Use Compatibility Data for mRNA-1273 Drug Product, **Table 35:** Lot 6006920001, 0.5 mg/mL, (Polycarbonate) Post 6 Hour Hold of Opened Multiple-Dose Vial

<b>T</b> 4	Acceptance Criteria		T . *4* . 14.	T	= 8h	<b>T</b> =	Γ = 24h	
Test	Initial	T8h and T24h	Initial*	RT	5°C	RT	5°C	
Appearance	Repo	ort result	White to o	ff-white dis	persion, essen	tially free of	particulates	
RNA content by AEX-HPLC		% Difference from Initial is						
Purity by RP-HPLC	m	ain peak area						
_	Report %Area for	each Impurity Group			%Area		20.	
	Impuri	ty Group 1						
Product related impurities by RP-HPLC	Impuri	ty Group 2		to off-white dispersion, essentially free of %Area				
5,14 14 16	Impuri	ty Group 3						
	Total i	impurities				RT tially free of partially fr		
In Vitro Translation								
% RNA encapsulation by Fluorescence (RiboGreen)								
Mean particle size by Dynamic light scattering								
Polydispersity by Dynamic light scattering	Repo	ort result						
Lipid content by UPLC-CAD			7,00	0,				
SM-102		·0g.						
Cholesterol		% Difference from						
DSPC		Initial is						
PEG2000-DMG		Me spir 4						
		RRT O			%Area			
	RI	RT						
Lipid impurities by UPLC-CAD	R	RT						
(Report RRT and % Area)	RI	RT				5°C RT sion, essentially free of p		
,	B.	RT						
	RI	RT						
pН					1	N/A		
Osmolality					1	N/A		

<sup>\*</sup> 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

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

T4	Accepta	nce Criteria	T-:4:-1+	T = 8h		T = 24h	
Test	Initial	T8h and T24h	Initial*	RT	5°C	RT	5°C
Appearance	Repo	ort result	White to o	off-white disp	ersion, essent	ially free of p	articulates
RNA content		% Difference from					
by AEX-HPLC Purity		Initial is					
by RP-HPLC	m	ain peak area					
	Report %Area for	each Impurity Group			%Area	C	
Th. 1 . 1 . 1 ! !!	Impurit	ty Group 1					
Product related impurities by RP-HPLC	Impuri	ty Group 2					
3, 3	Impurit	ty Group 3					
	Total i	impurities					
In Vitro Translation							
% RNA encapsulation by Fluorescence (RiboGreen)							
Mean particle size							
by Dynamic light scattering							
Polydispersity by Dynamic light scattering	Repo	ort result					
Lipid content by UPLC-CAD		0	7 201	0			
SM-102		20.					
Cholesterol		% Difference from					
DSPC		Initial is					
PEG2000-DMG		Ma Shirt					
	]	RRT O			%Area		
	RR	T					
Lipid impurities	RR	Á					
by UPLC-CAD (Report RRT and % Area)	RR	RT.					
(maparateria mine vo i mon)	RR	. \					
	RR	_					
pН					N	/A	
Osmolality					N.	/A	

<sup>\*</sup> 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,

Test	Acceptance Criteria Initial T4h, T8h, T12h		- Initial*	T = 4h		T = 8h		T = 12h	
				RT	5°C	RT	5°C	RT	, C
Purity by RP-HPLC		main peak area							
<u> </u>	Report %Area fo	or each Impurity Group			•	% Area	•	13/	
	Impur	rity Group 1							
Product related impurities by RP-HPLC	Impurity Group 2								
		rity Group 3							
In Vitro Relative Protein	Total	l impurities					F 0.7		
Expression <sup>a</sup>	Report Results					n/a 🎺	00/2		
y Fluorescence (RiboGreen) Mean particle size y Dynamic light scattering olydispersity y Dynamic light scattering	_								
	sed to suppo	iginally reported were a .60 was applied to this							

**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

T4	Accept	Acceptance Criteria		T = 4h		T = 8h		T =	12h
1 est	Initial	T4h, T8h, T12h	Initial*	RT	5°C	RT	5°C	RT	5°C
Purity by RP-HPLC		main peak area							
	Report %Area fo	Report %Area for each Impurity Group					:0		
by RP-HPLC  Product related impurities by RP-HPLC  In Vitro Relative Protein Expression  % RNA encapsulation by Fluorescence (RiboGreen) Mean particle size by Dynamic light scattering Polydispersity	Impurity Group 1 Impurity Group 2								
	Impu	Impurity Group 3							
	Total								
In Vitro Relative Protein	D	t D1t			<b>N</b> 7	·/ A	XO,		
Expression <sup>a</sup>	Kepe	ort Results			N	/A	3,00		
Mean particle size									
by Dynamic light scattering					() /				

<sup>\*</sup> 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

N/A = not required per the stability protocol

a) All relative protein expression absolute values originally reported were artificially low due to an eafter testing was performed. A correction factor of 1.60 was applied to this full dataset. a) All relative protein expression absolute values originally reported were artificially low due to an error on the reference material label for concentration, determined

**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	
1 cst	Initial	T4h, T8h, T12h	THIGH	RT	5°C	RT	5°C	RT	5°C
Purity	m	nain peak area							
by RP-HPLC		r each Impurity Group				% Area		(0)	
	_							1/0	
Product related impurities	Impuri	ity Group 2							
by RP-HPLC	Impuri	ity Group 3							
	Total	impurities							
In Vitro Relative Protein	Pana	out Dagulta			NI	/ A	XO,		
Expression a	Керо	or Results			14/	A Ø	700		
% RNA encapsulation by Fluorescence (RiboGreen)									
Product related impurities by RP-HPLC  In Vitro Relative Protein Expression a % RNA encapsulation by Fluorescence (RiboGreen) Mean particle size by Dynamic light scattering Polydispersity by Dynamic light scattering * Initial (T = 0) results refer to droom temperature for another 7 lN/A = not required per the stabil a) All relative protein expression concentration, determined after									
by Dynamic light scattering Polydispersity									
by Dynamic light scattering									
* Initial (T = 0) results refer to d	loses extracted afte	er vials were removed fi	rom -70°C sto	rage, allowed	to thaw for	1 hour at 25	°C, puncture	ed 4 times, and	I then h
N/A = not required per the stabil	lity protocol		4.	20%	01,				
a) All relative protein expression	absolute values or	riginally reported were	artificially lo	w due to an e	rror on the re	eference mat	erial label fo	or	
concentration, determined after	testing was perfor	rmed. A correction fact	or of 1.60 was	applied to the	nis full datase	et.			
	_		08	7, 0/N					
			110,42	CV.					
			SV. "OI,	VO.					
		· ?							
		-Mc	97, 70						
		Ø, <sup>9</sup>	.0.						
		100	0/01						
		2/2							
		Low Hill							
		11,110							
		36,00							
	_4	X . P							
	-00	10							
	-1164	200							
	55	).							
	7,40 -60								
	80 W								
	3 10								
	20								
X V									
200									
alli									
, Co									
and the same of th									
Ne									
CILL									
700									
<u> </u>									

<sup>\*</sup> 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

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.