

Stability Study: STY_01015 **Manufacturing Date:** 26-Feb-21
Lot Number: 6010121002 (7007621002) **Construct/mRNA Code:** mRNA-1273
Product: 60101 **Manufacturing Site:** Catalent, Bloomington, IN
Container: 10R Type I Equivalent Alkali Aluminosilicate Glass (Valor),
20 mm Stopper, 20 mm Cap

Table 1: Stability Data for Product 60101, Lot 6010121002 at -20°C ± 5°C

Test	Method	Shelf-life Acceptance Criteria	Release	3 Months	6 Months	12 Months
Appearance	Visual	White to off-white dispersion	White to off-white dispersion	-		
		May contain visible, white or translucent product-related particulates	Essentially free of particulates	-		
RNA Content	AEX-HPLC	(b) (4)		-		
Purity	RP-HPLC			(b) (4)		
Product-related Impurities	RP-HPLC					
% RNA Encapsulation	(b) (4)			-		
In Vitro Translation	In vitro translation / methionine labelling			-		

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Table 1: Stability Data for Product 60101, Lot 6010121002 at -20°C ± 5°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	3 Months	6 Months	12 Months	
pH	USP <791>	(b) (4)		-			
Particle Size	Dynamic light scattering			(b) (4)			
Polydispersity							
Lipid Content							
Cholesterol	UPLC-CAD			-			
DSPC				-			
PEG2000-DMG				-			
SM-102				-			
Lipid Impurities	UPLC-CAD			-			
				-			

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Table 1: Stability Data for Product 60101, Lot 6010121002 at -20°C ± 5°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	3 Months	6 Months	12 Months
Particulate Matter						
≥ 10 µm	USP <788> Method 2	(b) (4)		-	-	
≥ 25 µm				-	-	
Bacterial Endotoxins				-	-	
Container Closure Integrity	USP <1207>	Pass	-	-	-	
Sterility	USP <71>, Ph. Eur. 2.6.1	(b) (4)		-	-	

" - ": Not applicable per the stability protocol

Future Timepoint



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Table 2: Stability Data for Product 60101 Lot 6010121002 at -20°C ± 5°C

Condition	Time Point	Test	Parameter	Specification	Result
Release	Release	Lipid Impurities	(b) (4)		
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
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Table 3: Stability Data for Product 60101 Lot 6010121002 at 5°C ± 3°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	3 Months
Appearance	Visual	White to off-white dispersion	White to off-white dispersion	-	White to off-white dispersion
		May contain visible, white or translucent product-related particulates	Essentially free of particulates	-	Essentially free of particulates
RNA Content	AEX-HPLC	(b) (4)		-	(b) (4)
Purity	RP-HPLC			-	
				NT*	
Product-related Impurities	RP-HPLC			NT*	
				NT*	
				NT*	
% RNA Encapsulation	(b) (4)			-	
In Vitro Translation	In vitro translation / methionine labelling			-	

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Table 3: Stability Data for Product 60101 Lot 6010121002 at 5°C ± 3°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	3 Months
pH	USP <791>	(b) (4)		-	(b) (4)
Particle Size	Dynamic light scattering			NT*	
Polydispersity				NT*	
Lipid Content					
Cholesterol	UPLC-CAD			-	
DSPC				-	
PEG2000-DMG				-	
SM-102				-	
Lipid Impurities	UPLC-CAD			-	
				-	

NT*: Not Tested. Refer to QE-008189. " - ": Not applicable per the stability protocol

^a Purity result fell outside of the reference acceptance criteria

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Table 4: Stability Data for Product 60101 Lot 6010121002 at 5°C ± 3°C

Condition	Time Point	Test	Parameter	Specification	Result
Release	Release	Lipid Impurities	(b) (4)		
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			

Document Approvals
Approved Date: 15 Oct 2021

Task: Approval Task Verdict: Approve	(b) (6) [REDACTED] (b) (6) [REDACTED]@modernatx.com) Quality Control Approval 14-Oct-2021 01:10:05 GMT+0000
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