

Stability Study : STY_01038 **Manufacturing Date:** 7-Apr-21
Lot Number: 6008921001 (7007621005) **Construct/mRNA Code:** mRNA-1273
Product: 60089 **Manufacturing Site:** Baxter, Bloomington, IN
Container: 10R Corning Velocity Vial, 20 mm Stopper, 20 mm Cap

Table 1: Stability Data for Product 60089, Lot 6008921001 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)	(b) (4)		-		
In Vitro Translation	In vitro translation / methionine labelling			-		

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Table 1: Stability Data for Product 60089, Lot 6008921001 at -20°C ± 5°C (Continued)

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

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Table 1: Stability Data for Product 60089, Lot 6008921001 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	USP <85>, Ph. Eur. 2.6.14			-		
Sterility	USP <71>, Ph. Eur. 2.6.1			-		
Container Closure Integrity	USP <1207>	Pass	-	-		

" - ": Not applicable per the stability protocol

Future Timepoint

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Table 2: Stability Data for Product 60082, Lot 6008921001 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			
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 60089, Lot 6008921001 at 5°C ± 3°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	3 Month
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	-	Essentiall free of particulates
RNA Content	AEX-HPLC	(b) (4)		-	(b) (4)
Purity	RP-HPLC			(b) (4)	(b) (4)
Product-related Impurities	RP-HPLC			-	
% RNA Encapsulation	(b) (4)			-	
In Vitro Translation	translation / methionine labelling			-	

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Product:	60089	Manufacturing Site:	Baxter, Bloomington, IN
Container:	10R Corning Velocity Vial, 20 mm Stopper, 20 mm Cap		

Table 3: Stability Data for Product 60089, Lot 6008921001 at 5°C ± 3°C (Continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	3 Month
pH	USP <791>	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Particle Size	Dynamic light scattering				
Polydispersity					
Lipid Content					
SM-102	UPLC-CAD			-	
Cholesterol				-	
DSPC				-	
PEG2000-DMG				-	
Lipid Impurities	UPLC-CAD			-	
				-	
Sterility	USP <71>, Ph. Eur. 2.6.1	-	-		
Container Closure Integrity	USP <1207>	Pass	-	-	-

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Table 4: Individual Lipid Impurities Data for Product 60089, Lot 6008921001 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			
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: 13 Oct 2021

Task: Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Subject Matter Expert Approval 12-Oct-2021 14:37:28 GMT+0000
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Task: QA Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Quality Assurance Approval 13-Oct-2021 15:46:23 GMT+0000