

**Stability Study :** STY\_01066  
**Lot Number:** 6009921006 (7007621030)  
**Product:** 60099  
**Container:** 10R Ompi Glass Vial, 20 mm Stopper, 20 mm Cap

**Manufacturing Date:** 27-Apr-21  
**Construct/mRNA Code:** mRNA-1273  
**Manufacturing Site:** Catalent, Bloomington, IN

**Table 1: Stability Data for Product 60099, Lot 6009921006 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 dispersions	-				
		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 60099, Lot 6009921006 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							
<b>Lipid Content</b>							
SM-102	UPLC-CAD						
Cholesterol							
DSPC							
PEG2000-DMG							
Lipid Impurities	UPLC-CAD						

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Test	Method	Shelf-life Acceptance Criteria	Release	3 Months	6 Months	12 Months
<b>Particulate Matter</b>						
≥ 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

**Stability Study :** STY\_01066  
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**Table 2: Stability Data for Product 60099, Lot 6009921006 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			
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Release	Release	Lipid Impurities			

Document Approvals  
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Task: Approval Task Verdict: Approve	(b) (6) (b) (6) @modernatx.com Quality Control Approval 13-Oct-2021 01:25:15 GMT+0000
Task: Approval Task Verdict: Approve	(b) (6) (b) (6) @modernatx.com Subject Matter Expert Approval 13-Oct-2021 21:41:25 GMT+0000
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