

Stability Study : STY_01016
Lot Number: 6009821002
Product: 60098
Container: 10R Ompi RTU Glass Vial, 20 mm Stopper, 20 mm Cap

Manufacturing Date: 28-Feb-21
Construct/mRNA Code: mRNA-1273
Manufacturing Site: Catalent, Bloomington, IN

Table 1: Stability Data for Product 60098, Lot 6009821002 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 60098, Lot 6009821002 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						
SM-102	UPLC-CAD			-		
Cholesterol				-		
DSPC				-		
PEG2000-DMG				-		
Lipid Impurities	UPLC-CAD			-		
				-		

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Table 1: Stability Data for Product 60098, Lot 6009821002 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 60098, Lot 6009821002 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			
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Table 3: Stability Data for Product 60098, Lot 6009821002 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*	
				NT*	
% RNA Encapsulation	(b) (4)			-	
In Vitro Translation	In vitro translation / methionine labelling	-			

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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					
SM-102	UPLC-CAD			-	NT*
Cholesterol				-	NT*
DSPC				-	NT*
PEG2000-DMG				-	NT*
Lipid Impurities	UPLC-CAD			-	NT*
				-	NT*
Sterility	USP <71>, Ph. Eur. 2.6.1			-	-
Container Closure Integrity	USP <1207>	Pass	-	-	-

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



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Table 4: Individual Lipid Impurities Data for Product 60098, Lot 6009821002 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			

Document Approvals
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Task: Approval Task Verdict: Approve	(b) (6) [REDACTED] (b) (6) [REDACTED]@modernatx.com) Quality Control Approval 12-Oct-2021 20:49:52 GMT+0000
Task: Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Subject Matter Expert Approval 13-Oct-2021 19:48:37 GMT+0000
Task: QA Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Quality Assurance Approval 13-Oct-2021 20:48:16 GMT+0000