

Stability Study : STY_00899

Lot Number: 6007320010

Product: 60073

Container: 10R Glass Vial, 20 mm Stopper, 20 mm Cap

Manufacturing Date:

22Nov2020

Construct/mRNA Code:

mRNA-1273

Manufacturing Site:

Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60073, Lot 6007320010 at -20°C ± 5°C

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	3 Months	6 Months	9 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)		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 1: Stability Data for Product 60073, Lot 6007320010 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	3 Months	6 Months	9 Months	12 Months		
pH	USP <791>	(b) (4)		-	-					
Particle Size	Dynamic light scattering			(b) (4)	NT**					
Polydispersity					NT**					
Lipid Identification										
SM-102	UPLC-CAD			-	-					
Cholesterol				-	-					
DSPC				-	-					
PEG2000-DMG				-	-					
Lipid Content										
SM-102	UPLC-CAD			-	-					
Cholesterol				-	-					
DSPC				-	-					
PEG2000-DMG				-	-					
Lipid Impurities	UPLC-CAD			-	-					
				-	-					

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Table 1: Stability Data for Product 60073, Lot 6007320010 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	3 Months	6 Months	9 Months	12 Months
Particulate Matter								
≥ 10 µm	USP <788>	(b) (4)		-	-	-		
≥ 25 µm	Method 2			-	-	-		
Bacterial Endotoxins	USP <85>, Ph. Eur. 2.6.14			-	-	-		
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

^a Quantitation Limit less than 1

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Table 2: Stability Data for Product 60073, Lot 6007320010 at -20°C ± 5°C

Condition	Time Point	Test	Parameter	Shelf-Life Acceptance Criteria	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			

Task: Approval Task Verdict: Approve	(b) (6) [REDACTED] (b) (6) [REDACTED]@modernatx.com) Quality Control Approval 14-Oct-2021 01:09:23 GMT+0000
Task: Approval Task Verdict: Approve	(b) (6) [REDACTED] (b) (6) [REDACTED]@modernatx.com) Subject Matter Expert Approval 18-Oct-2021 14:49:44 GMT+0000
Task: QA Approval Task Verdict: Approve	(b) (6) [REDACTED] (b) (6) [REDACTED]@modernatx.com) Quality Assurance Approval 18-Oct-2021 17:46:23 GMT+0000