

Stability Study: STY_00883

Lot Number: 6007920001

Product: 60079

Container: 10R SiO2 Vial, 20 mm Stopper, 20 mm Cap

Manufacturing Date:

25Oct2020

Construct/mRNA Code:

mRNA-1273

Manufacturing Site:

Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60079, Lot 6007920001 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	NT*	NT*	White to off-white dispersion		
		May contain visible, white or translucent product-related particulates	Essentially free of particulates	NT*	NT*	Essentially free of particulates		
RNA Content	AEX-HPLC	(b) (4)		(b) (4)	NT*	(b) (4)		
Purity	RP-HPLC			NT*	(b) (4)			
Product-related Impurities	RP-HPLC			NT*				
				NT*				
				NT*				
				NT*				
% RNA Encapsulation	(b) (4)			(b) (4)				
In vitro Translation	In vitro translation / methionine labelling							

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Table 1: Stability Data for Product 60079, Lot 6007920001 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)		NT*	NT*	(b) (4)					
Particle Size	Dynamic light scattering			NT*	(b) (4)						
Polydispersity				NT*							
Lipid Identification											
SM-102	UPLC-CAD			(b) (4)	NT*						
Cholesterol					NT*						
DSPC					NT*						
PEG2000-DMG					NT*						
Lipid Content											
SM-102	UPLC-CAD				NT*						
Cholesterol					NT*						
DSPC					NT*						
PEG2000-DMG					NT*						
Lipid Impurities	UPLC-CAD				NT*						
					NT*						

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Table 1: Stability Data for Product 60079, Lot 6007920001 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> 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	-	-	-	-		

NT*: Not Tested, Refer to QE-005517 "-": Not applicable per the stability protocol

Future Timepoint

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Table 2: Stability Data for Product 60079, Lot 6007920001 at -20°C ± 5°C

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Table 2: Stability Data for Product 60079, Lot 6007920001 at -20°C ± 5°C (continued)

Condition	Time Point	Test	Parameter	Shelf-life Acceptance Criteria	Result
-20°C ± 5°C	1 Month	Lipid Impurities	(b) (4)		
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			
-20°C ± 5°C	6 Months	Lipid Impurities			

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Table 3: Stability Data for Product 60079, Lot 6007920001 at 25°C ± 2°C

Test	Method	Shelf-life Acceptance Criteria	Release	24 Hours	72 Hours
Purity	RP-HPLC	(b) (4)			
Product-related Impurities	RP-HPLC				
Particle Size	Dynamic light scattering				
Polydispersity					