

Stability Study : STY_00884
Lot Number: 6007920002
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 6007920002 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)			NT*	(b) (4)		
Purity	RP-HPLC	(b) (4)			NT*	(b) (4)		
Product-related Impurities	RP-HPLC	(b) (4)			NT*	(b) (4)		
					NT*			
					NT*			
					NT*			
% RNA Encapsulation	(b) (4)	(b) (4)			(b) (4)	(b) (4)		
In vitro Translation	In vitro translation / methionine labelling	(b) (4)			(b) (4)	(b) (4)		

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Table 1: Stability Data for Product 60079, Lot 6007920002 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			NT*	NT*			
Cholesterol				NT*	NT*			
DSPC				NT*	NT*			
PEG2000-DMG				NT*	NT*			
Lipid Content								
SM-102	UPLC-CAD			NT*	NT*			
Cholesterol				NT*	NT*			
DSPC				NT*	NT*			
PEG2000-DMG				NT*	NT*			
Lipid Impurities	UPLC-CAD			NT*	NT*			
				NT*	NT*			

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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 6007920002 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			
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Table 2: Stability Data for Product 60079, Lot 6007920002 at -20°C ± 5°C (continued)

Condition	Time Point	Test	Parameter	Shelf-Life Acceptance Criteria	Result
-20°C ± 5°C	6 Months	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			
-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 6007920002 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					