

Stability Study : STY_00900

Lot Number: 6007920003

Product: 60079

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

Manufacturing Date: 10Dec2020

Construct/mRNA Code: mRNA-1273

Manufacturing Site: Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60079, Lot 6007920003 at -20°C ± 5°C

Test	Method	Shelf-Life Acceptance Criteria	Release	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)			
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 60079, Lot 6007920003 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Months	6 Months	9 Months	12 Months
pH	USP <791>	(b) (4)		-		-	
Particle Size	Dynamic light scattering			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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Test	Method	Shelf-Life Acceptance Criteria	Release	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-008189 "-": Not applicable per the stability protocol

Future Timepoint

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Table 2: Stability Data for Product 60079, Lot 6007920003 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			
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Table 3: Stability Data for Product 60079, Lot 6007920003 at 5°C ± 3°C

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	3 Months	4 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*		(b) (4)
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 3: Stability Data for Product 60079, Lot 6007920003 at 5°C ± 3°C (continued)

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

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

NT**: Not Tested, Refer to QE-008189

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Table 4: Stability Data for Product 60079, Lot 6007920003 at 5°C ± 3°C

Condition	Time Point	Test	Parameter	Shelf-Life Acceptance	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 4: Stability Data for Product 60079, Lot 6007920003 at 5°C ± 3°C (continued)

Condition	Time Point	Test	Parameter	Shelf-Life Acceptance Criteria	Result
5°C ± 3°C	3 Months	Lipid Impurities	(b) (4)		
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			

Document Approvals
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