

Stability Study : STY_00888
Lot Number: 6008620007 (Catalent Lot 028L20)
Product: 60086
Container: 10R Valor RTS Vial

Manufacturing Date: 9-Dec-20
Construct/mRNA Code: mRNA-1273
Manufacturing Site: Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60086, Lot 6008620007 (Catalent Lot 028L20) at -20°C ± 5°C

Test	Parameter	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*	White to off-white dispersion	White to off-white dispersion		
		May contain visible, white or translucent product-related particulates	Essentially Free of particulates	NT*	Essentially Free of particulates	Essentially Free of particulates		
RNA Content	AEX-HPLC	(b) (4)		NT*	(b) (4)	(b) (4)		
Purity	RP-HPLC			NT*	NT**			
Product Related Impurities	RP-HPLC			NT*	NT**			
				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 60086, Lot 6008620007 (Catalent Lot 028L20) at -20°C ± 5°C (continued)

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

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Test	Parameter	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				-	-	-		
Sterility				-	-	-		
Container Closure Integrity	USP <1207>	Pass	-	-	-	-		

NT*: Not Tested, Refer to QE-005517 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 60086, Lot 6008620007 (Catalent Lot 028L20) 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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Condition	Time Point	Test	Parameter	Shelf-Life Acceptance Criteria	Result
-20°C ± 5°C	3 Months	Lipid Impurities	(b) (4)		
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 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			