

Stability Study : STY_00886
Lot Number: 6008620001 (Catalent Lot 025L20)
Product: 60086
Container: 10R Valor RTS Vial

Manufacturing Date: 25-Nov-20
Construct/mRNA Code: mRNA-1273
Manufacturing Site: Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60086, Lot 6008620001 (Catalent Lot 025L20) 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*	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 6008620001 (Catalent Lot 025L20) 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*	(b) (4)			
Particle Size	Dynamic light scattering			NT*				
Polydispersity				NT*				
Lipid Identification								
SM-102	UPLC-CAD	(b) (4)		NT*	NT**	(b) (4)		
Cholesterol				NT*	NT**			
DSPC				NT*	NT**			
PEG2000-DMG				NT*	NT**			
Lipid Content								
SM-102	UPLC-CAD	(b) (4)		NT*	NT**	(b) (4)		
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)	(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 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 6008620001 (Catalent Lot 025L20) 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			
-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			