

Stability Study : STY_00940

Lot Number: 6008520001

Product: 60085

Container: 10R Ompi Glass Vial, 20 mm Stopper, 20 mm Cap

Manufacturing Date: 01Jan2021

Construct/mRNA Code: mRNA-1273

Manufacturing Site: Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60085, Lot 6008520001 at -20°C ± 5°C

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Months	6 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)	(b) (4)		-					
In vitro Translation	In vitro translation / methionine labelling			-					

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Table 1: Stability Data for Product 60085, Lot 6008520001 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Months	6 Months	12 Months				
pH	USP <791>	(b) (4)		-						
Particle Size	Dynamic light scattering			(b) (4)						
Polydispersity										
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					(b) (4)		-		
								-		

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Table 1: Stability Data for Product 60085, Lot 6008520001 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Months	6 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	-	-		

"-": Not applicable per the stability protocol

Future Timepoint



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Table 2: Stability Data for Product 60085, Lot 6008520001 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 60085, Lot 6008520001 at 5°C ± 3°C

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	3 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**	
Product-related Impurities	RP-HPLC			NT**	
				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 60085, Lot 6008520001 at 5°C ± 3°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	3 Months
pH	USP < 791>	(b) (4)		-	(b) (4)
Particle Size	Dynamic light scattering	(b) (4)			
Polydispersity					
Lipid Identification					
SM-102	UPLC-CAD	(b) (4)		-	
Cholesterol				-	
DSPC				-	
PEG2000-DMG				-	
Lipid Content					
SM102	UPLC-CAD	(b) (4)		-	
Cholesterol				-	
DSPC				-	
PEG2000-DMG				-	
Lipid Impurities	UPLC-CAD	(b) (4)		-	
Lipid Impurities				-	
Sterility	USP <71>, Ph. Eur. 2.6.1	(b) (4)		-	-

NT*: Not Tested, Refer to QE-005517 NT**: Not Tested, refer to QE-008189 "-": Not applicable per the stability protocol

^a Assays were initiated outside of the 14-day test window (QE-008191)

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Table 4: Stability Data for Product 60085, Lot 6008520001 at 5°C ± 3°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			
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			
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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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