

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: Moderna Technology Center (MTC) - (b) (4)

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

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Month	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 60085, Lot 6008520001 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Month	6 Months	9 Months	12 Months
pH	USP <791>	(b) (4)		-			
Particle Size	Dynamic light scattering			(b) (4)			
Polydispersity							
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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Table 1: Stability Data for Product 60085, Lot 6008520001 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	3 Month	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	-	-			

"-": 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	(b) (4)				
Product-related Impurities	RP-HPLC	(b) (4)				
% RNA Encapsulation	(b) (4)	(b) (4)		-		
In vitro Translation	In vitro translation / methionine labelling	(b) (4)		-		

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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			-	
Cholesterol				-	
DSPC				-	
PEG2000-DMG				-	
Lipid Content					
SM102	UPLC-CAD			-	
Cholesterol				-	
DSPC				-	
PEG2000-DMG				-	
Lipid Impurities	UPLC-CAD			-	
Lipid Impurities				-	
Sterility	USP <71>, Ph. Eur. 2.6.1			-	

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

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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			
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			
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5°C ± 3°C	3 Months	Lipid Impurities			
5°C ± 3°C	3 Months	Lipid Impurities			