

**Stability Study:** STY\_01034 **Manufacturing Date:** 2-Apr-21  
**Lot Number:** 6008221003 (7007621004) **Construct/mRNA Code:** mRNA-1273  
**Product:** 60082 **Manufacturing Site:** Bloomington, IN  
**Container:** 10R Type I Equivalent Akali Aluminosilicate Glass (Valor), 20 mm  
 Stopper, 20 mm Cap

**Table 1: Stability Data for Product 60082, Lot 6008221003 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)		(b) (4)		
Product-related Impurities	RP-HPLC	(b) (4)				
		(b) (4)				
		(b) (4)				
% RNA Encapsulation	(b) (4)	(b) (4)		-		
In Vitro Translation	In vitro translation / methionine labelling	(b) (4)		-		

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**Table 1: Stability Data for Product 60082, Lot 6008221003 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)		(b) (4)				
Polydispersity								
<b>Lipid Content</b>								
SM-102	UPLC-CAD					-		
Cholesterol						-		
DSPC						-		
PEG2000-DMG						-		
Lipid Impurities	UPLC-CAD					-		
						-		

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**Table 1: Stability Data for Product 60082, Lot 6008221003 at -20°C ± 5°C (continued)**

Test	Method	Shelf-life Acceptance Criteria	Release	3 Months	6 Months	12 Months
<b>Particulate Matter</b>						
≥ 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



**Stability Study**                    **STY\_01034**                    **Manufacturing Date:**    2-Apr-21  
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**Table 2: Stability Data for Product 60082, Lot 6008221003 at -20°C ± 5°C**

Condition	Time Point	Test	Parameter	Specification	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 60082, Lot 6008221003 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				
% RNA Encapsulation	(b) (4)			-	
In vitro Translation	In vitro translation / methionine labelling			-	

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**Table 3: Stability Data for Product 60082, Lot 6008221003 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			NR	
Polydispersity				NR	
<b>Lipid Content</b>					
SM-102	UPLC-CAD			-	
Cholesterol				-	
DSPC				-	
PEG2000-DMG				-	
Lipid Impurities	UPLC-CAD			-	
				-	

" - ": Not applicable per the stability protocol NR: No result reported. See next timepoint to bracket result.

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**Table 4: Stability Data for Product 60082, Lot 6008221003 at 5°C ± 3°C**

Condition	Time Point	Test	Parameter	Specification	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 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			
5°C ± 3°C	3 Month	Lipid Impurities			

Document Approvals  
Approved Date: 14 Oct 2021

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