

Stability Study : STY_00844

Lot Number: 6007320005

Product: 60073

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

Manufacturing Date: 11Oct2020

Construct/mRNA Code: mRNA-1273

Manufacturing Site: Catalent Biologics, Bloomington, Indiana

Table 1: Stability Data for Product 60073, Lot 6007320005 at -20°C ± 5°C

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months	9 Months	12 Months	
Appearance	Visual	White to off-white dispersion	White to off-white dispersion	White to off-white dispersion	-	NT*	-	-	White to off-white dispersion			
		May contain visible, white or translucent product-related particulates	Essentially Free of Particulates	Essentially Free of Particulates	-	NT*	-	-	Essentially Free of Particulates			
RNA Content	AEX-HPLC	(b) (4)				-	NT*	-	-	(b) (4)		
Purity	RP-HPLC					NT*	NT*	(b) (4)	NT**			
Product-related Impurities	RP-HPLC					NT*	NT*		NT**			
						NT*	NT*		NT**			
						NT*	NT*		NT**			
% RNA Encapsulatio	(b) (4)					-	(b) (4)	-	-			
In vitro Translation	In vitro translation / methionine labelling					-		-	-			

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Table 1: Stability Data for Product 60073, Lot 6007320005 at -20°C ± 5°C (continued)

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months	9 Months	12 Months
pH	USP <791>	(b) (4)			-	NT*	-	-	(b) (4)		
Particle Size	Dynamic light scattering				NT*	NT*	(b) (4)	NT**			
Polydispersity					NT*	NT*		NT**			
Lipid Identification											
SM-102	UPLC-CAD				-	NT*	-	-			
Cholesterol					-	NT*	-	-			
DSPC					-	NT*	-	-			
PEG2000-DMG					-	NT*	-	-			
Lipid Content											
SM-102	UPLC-CAD				-	NT*	-	-			
Cholesterol					-	NT*	-	-			
DSPC					-	NT*	-	-			
PEG2000-DMG					-	NT*	-	-			
Lipid Impurities	UPLC-CAD				-	NT*	-	-			
					-	NT*	-	-			

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Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months	9 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	-	-	-	-	-	-	-		

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

Future Timepoint

^a % RNA Encapsulation method changed from (b) (4)) during the study. Methods are equivalent.

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Table 2: Stability Data for Product 60073, Lot 6007320005 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			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			
-20°C ± 5°C	1 Month	Lipid Impurities			

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Table 2: Stability Data for Product 60073, Lot 6007320005 at -20°C ± 5°C (continued)

Condition	Time Point	Test	Parameter	Shelf-Life Acceptance	Result
-20°C ± 5°C	6 Month	Lipid Impurities	(b) (4)		
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			
-20°C ± 5°C	6 Month	Lipid Impurities			

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Table 3: Stability Data for Product 60073, Lot 6007320005 at 5°C ± 3°C

Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months
Appearance	Visual	White to off-white dispersion.	White to off-white dispersion	White to off-white dispersion	-	NT*	-	-	White to off-white dispersion
		May contain visible, white or translucent product-related particulates	Essentially Free of Particulates	Essentially Free of Particulates	-	NT*	-	-	Essentially Free of Particulates
RNA Content	AEX-HPLC	(b) (4)			-	(b) (4)	-	-	(b) (4)
Purity	RP-HPLC				-	-	-	-	
Purity	RP-HPLC				NT*	NT*	NT*	NT**	
Product-related Impurities	RP-HPLC				NT*	NT*	NT*	NT**	
					NT*	NT*	NT*	NT**	
					NT*	NT*	NT*	NT**	
% RNA Encapsulatio	(b) (4)				-	(b) (4)	-	-	
In vitro Translation	In vitro translation / methionine labelling				-	(b) (4)	-	-	

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Test	Method	Shelf-Life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months
pH	USP <791>	(b) (4)			-	NT*	-	-	(b) (4)
Particle Size	Dynamic light scattering				NT*	NT*	NT*	NT**	
Polydispersity					NT*	NT*	NT*	NT**	
Lipid Identification									
SM102	UPLC-CAD				-	NT*	-	-	
Cholesterol					-	NT*	-	-	
DSPC					-	NT*	-	-	
PEG2000-DMG					-	NT*	-	-	
Lipid Content									
SM102	UPLC-CAD				-	NT*	-	-	
Cholesterol					-	NT*	-	-	
DSPC					-	NT*	-	-	
PEG2000-DMG					-	NT*	-	-	
Lipid Impurities	UPLC-CAD				-	NT*	-	-	
					-	NT*	-	-	
Sterility	USP <71>, Ph. Eur. 2.6.1				-	-	-	-	-

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

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Table 4: Stability Data for Product 60073, Lot 6007320005 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			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
Release	Release	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
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5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			
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Condition	Time Point	Test	Parameter	Shelf-Life Acceptance Criteria	Result
5°C ± 3°C	6 Month	Lipid Impurities	(b) (4)		
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			
5°C ± 3°C	6 Month	Lipid Impurities			