

Stability Study : STY_00690

Lot Number: 6007520003

Product: 60075

Container: 10R Glass Vial (Ompi), 20mm Stopper, 20mm

Manufacturing Date: 04Jun2020

Construct/mRNA Code: mRNA-1273

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

Table 1: Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	3 Months	6 Months	9 Months	12 Months	
Appearance	Visual	White to off-white dispersion.	White to off-white dispersion	White to off-white dispersion	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	Essentially Free of Particulates	Essentially Free of Particulates	Essentially Free of Particulates	NT*	Essentially Free of Particulates	Essentially Free of Particulates	
RNA Content	AEX-HPLC	(b) (4)				-	(b) (4)	NT*	(b) (4)	
Purity	RP-HPLC	(b) (4)						NT*	(b) (4)	
Product-related Impurities	RP-HPLC							(b) (4)		NT*
										NT*
										NT*
% RNA Encapsulation	(b) (4)	(b) (4)				NT*				
In vitro Translation	In vitro translation / methionine labelling	(b) (4)			-	(b) (4)				

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Table 1: Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C (continued)

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

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Table 1: Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	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	-	-	-	-	NA	-	Pass

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

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

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Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
Release	Release	Lipid Impurities	1	(b) (4)		
Release	Release	Lipid Impurities	1			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	6			
Release	Release	Lipid Impurities	6			

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Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
-60°C to -90°C	1 Month	Lipid Impurities	1	(b) (4)		
-60°C to -90°C	1 Month	Lipid Impurities	1			
-60°C to -90°C	1 Month	Lipid Impurities	2			
-60°C to -90°C	1 Month	Lipid Impurities	2			
-60°C to -90°C	1 Month	Lipid Impurities	3			
-60°C to -90°C	1 Month	Lipid Impurities	3			
-60°C to -90°C	1 Month	Lipid Impurities	4			
-60°C to -90°C	1 Month	Lipid Impurities	4			
-60°C to -90°C	3 Month	Lipid Impurities	1			
-60°C to -90°C	3 Month	Lipid Impurities	1			
-60°C to -90°C	3 Month	Lipid Impurities	2			
-60°C to -90°C	3 Month	Lipid Impurities	2			
-60°C to -90°C	3 Month	Lipid Impurities	3			
-60°C to -90°C	3 Month	Lipid Impurities	3			
-60°C to -90°C	3 Month	Lipid Impurities	4			
-60°C to -90°C	3 Month	Lipid Impurities	4			
-60°C to -90°C	3 Month	Lipid Impurities	5			
-60°C to -90°C	3 Month	Lipid Impurities	5			

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Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
-60°C to -90°C	9 Month	Lipid Impurities	1	(b) (4)		
-60°C to -90°C	9 Month	Lipid Impurities	1			
-60°C to -90°C	9 Month	Lipid Impurities	2			
-60°C to -90°C	9 Month	Lipid Impurities	2			
-60°C to -90°C	9 Month	Lipid Impurities	3			
-60°C to -90°C	9 Month	Lipid Impurities	3			
-60°C to -90°C	9 Month	Lipid Impurities	4			
-60°C to -90°C	9 Month	Lipid Impurities	4			
-60°C to -90°C	9 Month	Lipid Impurities	5			
-60°C to -90°C	9 Month	Lipid Impurities	5			
-60°C to -90°C	9 Month	Lipid Impurities	6			
-60°C to -90°C	9 Month	Lipid Impurities	6			
-60°C to -90°C	9 Month	Lipid Impurities	7			
-60°C to -90°C	9 Month	Lipid Impurities	7			

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Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at -60°C to -90°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
-60°C to -90°C	12 Month	Lipid Impurities	1	(b) (4)		
-60°C to -90°C	12 Month	Lipid Impurities	1			
-60°C to -90°C	12 Month	Lipid Impurities	2			
-60°C to -90°C	12 Month	Lipid Impurities	2			
-60°C to -90°C	12 Month	Lipid Impurities	3			
-60°C to -90°C	12 Month	Lipid Impurities	3			
-60°C to -90°C	12 Month	Lipid Impurities	4			
-60°C to -90°C	12 Month	Lipid Impurities	4			
-60°C to -90°C	12 Month	Lipid Impurities	5			
-60°C to -90°C	12 Month	Lipid Impurities	5			
-60°C to -90°C	12 Month	Lipid Impurities	6			
-60°C to -90°C	12 Month	Lipid Impurities	6			
-60°C to -90°C	12 Month	Lipid Impurities	7			
-60°C to -90°C	12 Month	Lipid Impurities	7			
-60°C to -90°C	12 Month	Lipid Impurities	8			
-60°C to -90°C	12 Month	Lipid Impurities	8			
-60°C to -90°C	12 Month	Lipid Impurities	9			
-60°C to -90°C	12 Month	Lipid Impurities	9			

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Table 3: Stability Data for Product 60075, Lot 6007520003 at -20°C ± 5°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4.5 Months	6 Months	9 Months	12 Months
Appearance	Visual	White to off-white dispersion.	White to off-white dispersion	White to off-white dispersion	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	Essentially Free of Particulates	Essentially Free of Particulates	Essentially Free of Particulates	-	NT*	Essentially Free of Particulates	Essentially Free of Particulates
RNA Content	AEX-HPLC	(b) (4)			-	(b) (4)	-	NT*	NT*	(b) (4)
Purity	RP-HPLC	(b) (4)						NT*	(b) (4)	
Product-related Impurities	RP-HPLC	(b) (4)						NT*		
								NT*		
								NT*		
% RNA Encapsulation	(b) (4)					(b) (4)	-	NT*		
In vitro Translation	In vitro translation / methionine labelling	(b) (4)			-		-	(b) (4)		

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Table 3: Stability Data for Product 60075, Lot 6007520003 at -20°C ± 5°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4.5 Months	6 Months	9 Months	12 Months	
pH	USP <791>	(b) (4)			-	(b) (4)	-	NT*	NT*	(b) (4)	
Particle Size	Dynamic light scattering	(b) (4)			-		(b) (4)	(b) (4)	(b) (4)		
Polydispersity					-						
Lipid Identification											
SM-102	UPLC-CAD	(b) (4)			-		-	NT*	NT*	NT**	
Cholesterol					-		NT*	NT*	NT**		
DSPC					-		NT*	NT*	NT**		
PEG2000-DMG					-		NT*	NT*	NT**		
Lipid Content											
SM-102	UPLC-CAD	(b) (4)			-		-	NT*	NT*	NT**	
Cholesterol					-		NT*	NT*	NT**		
DSPC					-		NT*	NT*	NT**		
PEG2000-DMG					-		NT*	NT*	NT**		
Lipid Impurities	UPLC-CAD	(b) (4)			-		-	NT*	NT*	NT**	
					-	NT*	NT*	NT**			

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Table 3: Stability Data for Product 60075, Lot 6007520003 at -20°C ± 5°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	3 Months	4.5 Months	6 Months	9 Months	12 Months
Osmolality	USP <785> Freezing Point Depression	(b) (4)	(b) (4)	-	-	-	-	NT*	-	-

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

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: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at -20°C ± 5°C

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
Release	Release	Lipid Impurities	1	(b) (4)		
Release	Release	Lipid Impurities	1			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	6			
Release	Release	Lipid Impurities	6			

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

Table 4: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at -20°C ± 5°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
-20°C ± 5°C	1 Month	Lipid Impurities	1	(b) (4)		
-20°C ± 5°C	1 Month	Lipid Impurities	1			
-20°C ± 5°C	1 Month	Lipid Impurities	2			
-20°C ± 5°C	1 Month	Lipid Impurities	2			
-20°C ± 5°C	1 Month	Lipid Impurities	3			
-20°C ± 5°C	1 Month	Lipid Impurities	3			
-20°C ± 5°C	1 Month	Lipid Impurities	4			
-20°C ± 5°C	1 Month	Lipid Impurities	4			
-20°C ± 5°C	1 Month	Lipid Impurities	5			
-20°C ± 5°C	1 Month	Lipid Impurities	5			
-20°C ± 5°C	3 Month	Lipid Impurities	1			
-20°C ± 5°C	3 Month	Lipid Impurities	1			
-20°C ± 5°C	3 Month	Lipid Impurities	2			
-20°C ± 5°C	3 Month	Lipid Impurities	2			
-20°C ± 5°C	3 Month	Lipid Impurities	3			
-20°C ± 5°C	3 Month	Lipid Impurities	3			
-20°C ± 5°C	3 Month	Lipid Impurities	4			
-20°C ± 5°C	3 Month	Lipid Impurities	4			
-20°C ± 5°C	3 Month	Lipid Impurities	5			
-20°C ± 5°C	3 Month	Lipid Impurities	5			

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

Table 5: Stability Data for Product 60075, Lot 6007520003 at 5°C ± 3°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	2.5 Months	3 Months	4 Months	6 Months
Appearance	Visual	White to off-white dispersion.	White to off-white dispersion	White to off-white dispersion	White to off-white dispersion	White to off-white dispersion	White to off-white dispersion	White to off-white dispersion	NT*
		May contain visible, white or translucent product-related particulates	Essentially Free of Particulates	Essentially Free of Particulates	Essentially Free of Particulates	Essentially Free of Particulates	Essentially Free of Particulates	Essentially Free of Particulates	NT*
RNA Content	AEX-HPLC	(b) (4)			-	-	(b) (4)	-	(b) (4)
Purity	RP-HPLC	(b) (4)							
Product-related Impurities	RP-HPLC								
% RNA Encapsulation	(b) (4)	(b) (4)			-	-	(b) (4)	-	NT*
In vitro Translation	In vitro translation / methionine labelling				-	-		-	(b) (4)

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

Table 5: Stability Data for Product 60075, Lot 6007520003 at 5°C ± 3°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	2.5 Months	3 Months	4 Months	6 Months
pH	USP <791>	(b) (4)			-	-	(b) (4)	-	(b) (4)
Particle Size	Dynamic light scattering	(b) (4)							NT*
Polydispersity									NT*
Lipid Identification									
SM-102	UPLC-CAD	(b) (4)			-	-	(b) (4)	-	NT*
Cholesterol					-	-		-	NT*
DSPC					-	-		-	NT*
PEG2000-DMG					-	-		-	NT*
Lipid Content									
SM-102	UPLC-CAD	(b) (4)			-	-	(b) (4)	-	NT*
Cholesterol					-	-		-	NT*
DSPC					-	-		-	NT*
PEG2000-DMG					-	-		-	NT*
Lipid Impurities	UPLC-CAD	(b) (4)			-	-	(b) (4)	-	NT*
					-	-		-	NT*

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

Table 5: Stability Data for Product 60075, Lot 6007520003 at 5°C ± 3°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Months	2.5 Months	3 Months	4 Months	6 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			-	-	-	-	-	

"-": Not applicable per the stability protocol

NT*: 5°C ± 3°C, 6M: Appearance, % Encapsulation, and Lipid Identification, Content and Impurities were not completed. Refer to QE-005517

^a Tested with (b) (4) method

^b Purity result fell outside of the reference acceptance criteria per QE-010680.

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

Table 6: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at 5°C ± 3°C

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
Release	Release	Lipid Impurities	1	(b) (4)		
Release	Release	Lipid Impurities	1			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	6			
Release	Release	Lipid Impurities	6			

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

Table 6: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at 5°C ± 3°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
5°C ± 3°C	1 Month	Lipid Impurities	1	(b) (4)		
5°C ± 3°C	1 Month	Lipid Impurities	1			
5°C ± 3°C	1 Month	Lipid Impurities	2			
5°C ± 3°C	1 Month	Lipid Impurities	2			
5°C ± 3°C	1 Month	Lipid Impurities	3			
5°C ± 3°C	1 Month	Lipid Impurities	3			
5°C ± 3°C	1 Month	Lipid Impurities	4			
5°C ± 3°C	1 Month	Lipid Impurities	4			
5°C ± 3°C	1 Month	Lipid Impurities	5			
5°C ± 3°C	1 Month	Lipid Impurities	5			
5°C ± 3°C	3 Month	Lipid Impurities	1			
5°C ± 3°C	3 Month	Lipid Impurities	1			
5°C ± 3°C	3 Month	Lipid Impurities	2			
5°C ± 3°C	3 Month	Lipid Impurities	2			
5°C ± 3°C	3 Month	Lipid Impurities	3			
5°C ± 3°C	3 Month	Lipid Impurities	3			
5°C ± 3°C	3 Month	Lipid Impurities	4			
5°C ± 3°C	3 Month	Lipid Impurities	4			
5°C ± 3°C	3 Month	Lipid Impurities	5			
5°C ± 3°C	3 Month	Lipid Impurities	5			
5°C ± 3°C	3 Month	Lipid Impurities	6			
5°C ± 3°C	3 Month	Lipid Impurities	6			

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

Table 7: Stability Data for Product 60075, Lot 6007520003 at 25°C ± 2°C

Test	Method	Shelf-life Acceptance Criteria	Release	24 Hours	72 Hours
Appearance	Visual	White to off-white dispersion.	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	Essentially Free of Particulates
RNA Content	AEX-HPLC	(b) (4)			
Purity	RP-HPLC				
Product-related Impurities	RP-HPLC				
% RNA Encapsulation	(b) (4)				
In vitro Translation	In vitro translation / methionine labelling				

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Table 7: Stability Data for Product 60075, Lot 6007520003 at 25°C ± 2°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	24 Hours	72 Hours
pH	USP <791>	(b) (4)			
Particle Size	Dynamic light scattering				
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				

^a Tested with (b) (4) method

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Table 8: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at 25°C ± 2°C

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
Release	Release	Lipid Impurities	1	(b) (4)		
Release	Release	Lipid Impurities	1			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	2			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	3			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	4			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	5			
Release	Release	Lipid Impurities	6			
Release	Release	Lipid Impurities	6			

Stability Study : STY_00690

Lot Number: 6007520003

Product: 60075

Container: 10R Glass Vial (Ompi), 20mm Stopper, 20mm

Manufacturing Date: 04Jun2020

Construct/mRNA Code: mRNA-1273

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

Table 8: Lipid Impurity Stability Data for Product 60075, Lot 6007520003 at 25°C ± 2°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
25°C ± 2°C	24 Hours	Lipid Impurities	1	(b) (4)		
25°C ± 2°C	24 Hours	Lipid Impurities	1			
25°C ± 2°C	24 Hours	Lipid Impurities	2			
25°C ± 2°C	24 Hours	Lipid Impurities	2			
25°C ± 2°C	24 Hours	Lipid Impurities	3			
25°C ± 2°C	24 Hours	Lipid Impurities	3			
25°C ± 2°C	24 Hours	Lipid Impurities	4			
25°C ± 2°C	24 Hours	Lipid Impurities	4			
25°C ± 2°C	24 Hours	Lipid Impurities	5			
25°C ± 2°C	24 Hours	Lipid Impurities	5			
25°C ± 2°C	72 Hours	Lipid Impurities	1			
25°C ± 2°C	72 Hours	Lipid Impurities	1			
25°C ± 2°C	72 Hours	Lipid Impurities	2			
25°C ± 2°C	72 Hours	Lipid Impurities	2			
25°C ± 2°C	72 Hours	Lipid Impurities	3			
25°C ± 2°C	72 Hours	Lipid Impurities	3			
25°C ± 2°C	72 Hours	Lipid Impurities	4			
25°C ± 2°C	72 Hours	Lipid Impurities	4			
25°C ± 2°C	72 Hours	Lipid Impurities	5			
25°C ± 2°C	72 Hours	Lipid Impurities	5			

Document Approvals
Approved Date: 13 Oct 2021

Task: Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Quality Control Approval 13-Oct-2021 19:01:51 GMT+0000
Task: Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Subject Matter Expert Approval 13-Oct-2021 19:08:58 GMT+0000
Task: QA Approval Task Verdict: Approve	(b) (6) [REDACTED], (b) (6) [REDACTED]@modernatx.com) Quality Assurance Approval 13-Oct-2021 19:57:10 GMT+0000