

Stability Study : STY_00689

Lot Number: 6007520002

Product: 60075

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

Manufacturing Date: 02-Jun-2020

Construct/mRNA Code: mRNA-1273

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

Table 1: Stability Data for Product 60075, Lot 6007520002 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)	(b) (4)	
Purity	RP-HPLC	(b) (4)				(b) (4)	NT*	(b) (4)	
Product-related Impurities	RP-HPLC						NT*		
							NT*		
							NT*		
							NT*		
% RNA Encapsulation	(b) (4)						NT*		
In vitro Translation	In vitro translation / methionine labelling	-							

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Table 1: Stability Data for Product 60075, Lot 6007520002 at -60°C to -90°C (continued)

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

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(b) (4)

Table 1: Stability Data for Product 60075, Lot 6007520002 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	-	-	-	-	-	-	Pass

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

NT*: Not Tested, Refer to QE-005517

"-": Not applicable per the stability protocol

Future Timepoint

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

Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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			

Stability Study : STY_00689

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Manufacturing Site: Moderna Technology Center (MTC) -

(b) (4)

Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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			

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

Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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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Manufacturing Site: Moderna Technology Center (MTC)

(b) (4)

Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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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Construct/mRNA Code: mRNA-1273

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Table 3: Stability Data for Product 60075, Lot 6007520002 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)					-	NT*	NT*	NT**
Purity	RP-HPLC						(b) (4)	(b) (4)		
Product-related Impurities	RP-HPLC									
% RNA Encapsulation	(b) (4)						-			
In vitro Translation	In vitro translation / methionine labelling						-			

Stability Study : STY_00689

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

Table 3: Stability Data for Product 60075, Lot 6007520002 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)		
Polydispersity							-				
Lipid Identification											
SM-102	UPLC-CAD				-		-	NT*	NT*	NT**	
Cholesterol					-		-	NT*	NT*	NT**	
DSPC					-		-	NT*	NT*	NT**	
PEG2000-DMG					-		-	NT*	NT*	NT**	
Lipid Content											
SM-102	UPLC-CAD				-		-	NT*	NT*	NT**	
Cholesterol					-		-	NT*	NT*	NT**	
DSPC					-		-	NT*	NT*	NT**	
PEG2000-DMG					-		-	NT*	NT*	NT**	
Lipid Impurities	UPLC-CAD				-		-	NT*	NT*	NT**	
		-	-	NT*	NT*	NT**					

Stability Study : STY_00689

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Construct/mRNA Code: mRNA-1273

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Table 3: Stability Data for Product 60075, Lot 6007520002 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)		-	-	-	-	NT*	-	-

a %RNA Encapsulation method changed from (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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(b) (4)

Table 4: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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			
Release	1 Month	Lipid Impurities	1			
Release	1 Month	Lipid Impurities	1			
Release	1 Month	Lipid Impurities	2			

Stability Study : STY_00689

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Construct/mRNA Code: mRNA-1273

Manufacturing Site: Moderna Technology Center (MTC)

(b) (4)

Table 4: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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	2	(b) (4)		
-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	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			

Stability Study : STY_00689

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

Table 5: Stability Data for Product 60075, Lot 6007520002 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)	-	(b) (4)
Purity	RP-HPLC	(b) (4)			(b) (4)	(b) (4)	(b) (4)	(b) (4)	NT*
Product-related Impurities	RP-HPLC								NT*
									NT*
									NT*
% RNA Encapsulation	(b) (4)	(b) (4)			-	-	(b) (4)	-	NT*
In vitro Translation	In vitro translation / methionine labelling				-	-		-	(b) (4)

Stability Study : STY_00689

Lot Number: 6007520002

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Manufacturing Date: 02-Jun-2020

Construct/mRNA Code: mRNA-1273

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Table 5: Stability Data for Product 60075, Lot 6007520002 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)	-	NT*											
Particle Size	Dynamic light scattering				(b) (4)															
Polydispersity								NT*												
Lipid Identification								(b) (4)												
SM-102	UPLC-CAD				-	-	-							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*

Stability Study : STY_00689

Lot Number: 6007520002

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Manufacturing Date: 02-Jun-2020

Construct/mRNA Code: mRNA-1273

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

Table 5: Stability Data for Product 60075, Lot 6007520002 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			-	-	-	-	-	

^a Tested with (b) (4)

NT*: Not Tested, Refer to QE-005517

"-": Not applicable per the stability protocol

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Construct/mRNA Code: mRNA-1273

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

Table 6: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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			

Stability Study : STY_00689

Lot Number: 6007520002

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Manufacturing Date: 02-Jun-2020

Construct/mRNA Code: mRNA-1273

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

Table 6: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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	1 Month	Lipid Impurities	6			
5°C ± 3°C	1 Month	Lipid Impurities	6			
5°C ± 3°C	1 Month	Lipid Impurities	7			
5°C ± 3°C	1 Month	Lipid Impurities	7			

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

Table 6: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 at 5°C ± 3°C (continued)

Condition	Time Point	Test	Replicate ID	Parameter	Shelf-life Acceptance Criteria	Result
5°C ± 3°C	3 Month	Lipid Impurities	1	(b) (4)		
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			
5°C ± 3°C	3 Month	Lipid Impurities	7			
5°C ± 3°C	3 Month	Lipid Impurities	7			
5°C ± 3°C	3 Month	Lipid Impurities	8			
5°C ± 3°C	3 Month	Lipid Impurities	8			

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

Table 7: Stability Data for Product 60075, Lot 6007520002 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				

Stability Study : STY_00689

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(b) (4)

Table 7: Stability Data for Product 60075, Lot 6007520002 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)

"-": Not applicable per the stability protocol

Stability Study : STY_00689

Lot Number: 6007520002

Product: 60075

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

Manufacturing Date: 02-Jun-2020

Construct/mRNA Code: mRNA-1273

Manufacturing Site: Moderna Technology Center (MTC)

(b) (4)

Table 8: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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_00689

Lot Number: 6007520002

Product: 60075

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

Manufacturing Date: 02-Jun-2020

Construct/mRNA Code: mRNA-1273

Manufacturing Site: Moderna Technology Center (MTC)

(b) (4)

Table 8: Lipid Impurity Stability Data for Product 60075, Lot 6007520002 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
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