

Stability Study : STY_00716

Manufacturing Date: 25June2020

Lot Number: 6007520004

Construct/mRNA Code: mRNA-1273

Product: 60075

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

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

Table 1: Stability Data for Product 60075, Lot 6007520004 at -60°C to -90°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Month	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	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	Essentially free of particulates	Essentially free of particulates	
RNA Content	AEX-HPLC	(b) (4)			-	(b) (4)			
Purity	RP-HPLC	(b) (4)					NT*	NT**	
Product-related Impurities	RP-HPLC						NT*	NT**	
							NT*	NT**	
							NT*	NT**	
% RNA Encapsulation	(b) (4)	(b) (4)					(b) (4)		
In vitro Translation	In vitro translation / methionine labelling	(b) (4)			-	(b) (4)			

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Table 1: Stability Data for Product 60075, Lot 6007520004 at -60°C to -90°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Month	3 Months	6 Months	9 Months	12 Months			
pH	USP <791>	(b) (4)			-	(b) (4)	NT*	(b) (4)				
Particle Size	Dynamic light scattering				(b) (4)		NT*	NT**				
Polydispersity							NT*	NT**				
Lipid Identification												
SM-102	UPLC-CAD	(b) (4)			-		NT*	NT**				
Cholesterol					-		NT*	NT**				
DSPC					-		NT*	NT**				
PEG2000-DMG					-		NT*	NT**				
Lipid Content												
SM102	UPLC-CAD				(b) (4)			-	NT*	NT**		
Cholesterol								-	NT*	NT**		
DSPC								-	NT*	NT**		
PEG2000-DMG								-	NT*	NT**		
Lipid Impurities	UPLC-CAD							(b) (4)			-	NT*
		-	NT*	NT**								

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Table 1: Stability Data for Product 60075, Lot 6007520004 at -60°C to -90°C (continued)

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Month	3 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	(b) (4)		-	-	-	-	-	
Container Closure Integrity	USP <1207>	Pass	-	-	-	-	-	-	
Osmolality	USP <785> Freezing Point Depression	(b) (4)		-	-	-	-	-	

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

Future Timepoint

NT**: Not Tested, Refer to QE-008189

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

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

Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520004 at -60°C to -90°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			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			
-60°C to -90°C	1 Month	Lipid Impurities			

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

Table 2: Lipid Impurity Stability Data for Product 60075, Lot 6007520004 at -60°C to -90°C (continued)

Condition	Time Point	Test	Parameter	Shelf-life Acceptance Criteria	Result
-60°C to -90°C	3 Months	Lipid Impurities	(b) (4)		
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			
-60°C to -90°C	3 Months	Lipid Impurities			

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

Table 3: Stability Data for Product 60075, Lot 6007520004 at -20°C ± 5°C

Test	Method	Shelf-life Acceptance Criteria	Release	1 Month	2 Month	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	-	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	-	Essentially free of particulates	Essentially free of particulates	
RNA Content	AEX-HPLC	(b) (4)			-	(b) (4)	-	NT*	NT**	
Purity	RP-HPLC	(b) (4)						NT*	NT**	
Product-related Impurities	RP-HPLC							NT*	NT**	
								NT*	NT**	
								NT*	NT**	
% RNA Encapsulation	(b) (4)	(b) (4)			(b) (4)	(b) (4)	-	(b) (4)		
In vitro Translation	In vitro translation / methionine labelling				-		-			

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

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

Table 3: Stability Data for Product 60075, Lot 6007520004 at -20°C ± 5°C (Continued)

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

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

Table 3: Stability Data for Product 60075, Lot 6007520004 at -20°C ± 5°C (Continued)

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

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

Future Timepoint

NT**: Not Tested, Refer to QE-008189

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

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

Table 4: Lipid Impurity Stability Data for Product 60075, Lot 6007520004 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			
-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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Manufacturing Site: Moderna Technology Center (MTC) - (b) (4)

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

Table 4: Lipid Impurity Stability Data for Product 60075, Lot 6007520004 at -20°C ± 5°C (continued)

Condition	Time Point	Test	Parameter	Shelf-life Acceptance Criteria	Result
-20°C ± 5°C	3 Months	Lipid Impurities	(b) (4)		
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			
-20°C ± 5°C	3 Months	Lipid Impurities			

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

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

Table 5: Stability Data for Product 60075, Lot 6007520004 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	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	Essentially free of particulates	Essentially free of particulates	Essentially free of particulates	
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)
In vitro Translation	In vitro translation / methionine labelling	(b) (4)			-	-	(b) (4)	-		

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Product: 60075

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

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

Table 5: Stability Data for Product 60075, Lot 6007520004 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)	(b) (4)				
Polydispersity								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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Lot Number: 6007520004

Construct/mRNA Code: mRNA-1273

Product: 60075

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

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

Table 5: Stability Data for Product 60075, Lot 6007520004 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			-	-	-	-	-	

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

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

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Product: 60075

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

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

Table 6: Stability Data for Product 60075, Lot 6007520004 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			
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			
5°C ± 3°C	1 Month	Lipid Impurities			
5°C ± 3°C	1 Month	Lipid Impurities			

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Manufacturing Site: Moderna Technology Center (MTC)

(b) (4)

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

Table 6: Stability Data for Product 60075, Lot 6007520004 at 5°C ± 3°C (continued)

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

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Product: 60075

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

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

Table 7: Stability Data for Product 60075, Lot 6007520004 at 25°C ± 2°C

Test	Method	Shelf-life Acceptance Criteria	Release	24 Hours	72 Hours
Appearance	Visual	(b) (4)			
RNA Content	AEX-HPLC				
Purity	RP-HPLC				
Product-related Impurities	RP-HPLC				
% RNA Encapsulation	(b) (4)				
In vitro Translation	In vitro translation / methionine labelling				

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

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

Table 7: Stability Data for Product 60075, Lot 6007520004 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				

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

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

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Product: 60075

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

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

Table 8: Lipid Impurity Stability Data for Product 60075, Lot 6007520004 at 25°C ± 2°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			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	24 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			
25°C ± 2°C	72 Hours	Lipid Impurities			