

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R Velocity Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	023F21A		
Moderna Lot Number:	7006821209	Specification:	SPC-1128
Date of Manufacture:	09Jun2021	Expiry Date:	09Jan2022

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	White to off-white dispersion.	White to off-white dispersion
		Appearance - Particulates	May contain visible, white or translucent product-related particles	Essentially Free of Particulates
Concentration	SOP-0999	RNA Content	(b) (4) (Target: 0. 20 mg/mL)	
Identity	SOP-1032	Identity	(b) (4)	
Purity	SOP-0996	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-1000	% Encapsulation		
In vitro Translation	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0998	Particle Size		
		Polydispersity		
Lipid Identification	SOP-1001	SM102		

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FDA-CBER-2022-1614-3815473



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Manufacturer Lot:	023F21A		
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Date of Manufacture:	09Jun2021	Expiry Date:	09Jan2022

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		Cholesterol	(b) (4)	
		DSPC		
		PEG-DMG		
		SM102		
Lipid Impurities		Cholesterol		
		DSPC		
		PEG-DMG		
		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		% Area 5		
		% Area 6		
		% Area 7		
		% Area 8		
		% Area 9		
		% Area 10		
		RRT 1		

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Manufacturer Lot:	023F21A		
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Product Attribute	Method	Parameter	Specification	Result
		RRT 2	(b) (4)	
		RRT 3		
		RRT 4		
		RRT 5		
		RRT 6		
		RRT 7		
		RRT 8		
		RRT 9		
		RRT 10		
		% Total Impurities		
Particulate Matter	SOP-0509	25 µm particles per container		
		10 µm particles per container		
Container Content	SOP-0950	Container Content	>= 5.0 mL (>= 10 doses of 0.5 mL from 1 vial)	(b) (4)
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	USP <71>	Sterility		

This material meets specification: Yes

Revision History: 1.0 Original

Labeled Drug Product Lot Numbers: 7006521124 (Moderna), 023F21A (Catalent)

Unlabeled Drug Product Lot Numbers: 6010721002 (Moderna), 023F21 (Catalent)

Drug Substance Manufacturer: Moderna, Norwood, MA

Drug Substance Lot Number: 5007521281

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FDA-CBER-2022-1614-3815475



CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R Velocity Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	023F21A		
Moderna Lot Number:	7006821209	Specification:	SPC-1128
Date of Manufacture:	09Jun2021	Expiry Date:	09Jan2022

Product Attribute	Method	Parameter	Specification	Result
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This lot of drug product was received and tested under Moderna lot # 7006521124 according to SPC-1128. Moderna Labeled Drug Product lot # 7006521124 (Catalent lot # 023F21A) is equivalent to Moderna Labeled Drug Product lot # 7006821209 (Catalent lot # 023F21A) sourced from Moderna Unlabeled Drug Product lot # 6010721002. Refer to change control QE-005351 for the change in part number from 70065 to 70068 for the drug product designated for EU supply. CoA is being generated against the US specifications (SPC-1128) for submission purposes only under part number 70065. Final CoA will be generated under part number 70068 by the applicable testing sites as per registration upon EMA approval.

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FDA-CBER-2022-1614-3815476

Document Approvals
Approved Date: 29 Jul 2021

Approval Verdict: Approved	(b) (6) [REDACTED] (b) (6) @modernatx.com) Quality Control Approval 29-Jul-2021 17:59:32 GMT+0000
QA Approval Verdict: Approved	(b) (6) [REDACTED] (b) (6) @modernatx.com) Quality Assurance Approval 29-Jul-2021 18:06:25 GMT+0000