

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20-2A		
Moderna Lot Number:	7006520007	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25Feb2021

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	Concentration	(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		
		Cholesterol		

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FDA-CBER-2022-1614-3815203



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

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

This material meets specification: Yes

Revision History:

1.0 - Original Certificate of Analysis, Unlabeled Drug Product Lot: 6007920002

2.0 - Added Drug Substance Manufacturer Information in lot revision history, corrected lot number to 025J20-2A (from 025J20-2)

Drug Substance Manufacturer: Moderna, Norwood, MA

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Document Approvals
Approved Date: 16 Dec 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 16-Dec-2020 16:58:07 GMT+0000
QA Approval Verdict: Approved	(b) (6) , (b) (6) @modernatx.com) Quality Assurance Approval 16-Dec-2020 17:45:34 GMT+0000