

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R Valor Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025L20A		
Moderna Lot Number:	7006520013	Specification:	SPC-1128
Date of Manufacture:	25Nov2020	Expiry Date:	25Jun2021

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		
		Cholesterol		

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FDA-CBER-2022-1614-3815223



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Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R Valor Glass Vial, 20 mm Stopper, 20 mm Cap
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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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		RRT 5		
		% Total Impurities		
Particulate Matter	SOP-0509	10 µm particles per container		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R Valor Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025L20A		
Moderna Lot Number:	7006520013	Specification:	SPC-1128
Date of Manufacture:	25Nov2020	Expiry Date:	25Jun2021

Product Attribute	Method	Parameter	Specification	Result
		25 µm particles per container	(b) (4)	
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one 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
2.0 - Corrected particle size acceptance criteria to 80 - 180nm (from 80 - 160nm)
Unlabeled Drug Product Lot 6008620001
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 21:25:02 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 16-Dec-2020 21:26:45 GMT+0000