



One Moderna Way • Norwood, MA 02062
Phone 617.714.6500 • Fax 617.583.1998

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70076
Manufacturer Name:	Baxter	Container/Closure:	10R Valor Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	939599		
Moderna Lot Number:	7007621003	Specification:	SPC-1353
Date of Manufacture:	27Mar2021	Expiry Date:	27Oct2021

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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Page 1 of 2

Document Number: VV-QUAL-005288 eDMS Version: 1.0 FDA-CBER-2022-1614-3815257
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Product Attribute	Method	Parameter	Specification	Result
Lipid Content		DSPC	(b) (4)	
		PEG-DMG		
		SM102		
		Cholesterol		
Lipid Impurities		DSPC		
		PEG-DMG		
		%Area 1		
		%Area 2		
		%Area 3		
		%Area 4		
		RRT 1		
		RRT 2		
Particulate Matter	SOP-0509	RRT 3		
		RRT 4		
		% Total Impurities		
		≥ 10 µm particles per container		
Container Content	SOP-1299	≥ 25 µm particles per container		
		Container Content		(b) (4)
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	USP <71>	Sterility		

This material meets specification: Yes

Revision History:

1.0 – Original

Unlabeled Drug Product Lot Numbers: 6008221002 (Moderna), 939596 (Baxter)
Drug Substance Manufacturer: Moderna, Norwood, MA
Drug Substance Lot Number: 5007521132

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Page 2 of 2
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FDA-CBER-2022-1614-3815258
Page 2 of 3

Document Approvals
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QA Approval Verdict: Approved	(b) (6) (b) (6) modernatx.com) Quality Assurance Approval 04-May-2021 21:27:35 GMT+0000