



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

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60098
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	022B21		
Moderna Lot Number:	6009821002	Specification:	SPC-1366
Date of Manufacture:	28Feb2021	Expiry Date:	28Sep2021

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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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		
Particulate Matter	SOP-0509	RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		% Total Impurities		
Container Content	SOP-1229	≥ 10 µm particles per container		
		≥ 25 µm particles per container		
Bacterial Endotoxins	USP <85>	Container Content		(b) (4)
Sterility	USP <71>	Syringe/Needle		
		Option A: 15 doses of 0.5 mL from 1 vial Option B: 13 doses of 0.5 mL from 1 vial		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	USP <71>	Sterility		

This material meets specification: Yes

Revision History:

1.0 – Original
2.0 – Correct part number to 60098
Labeled Drug Product Lot Numbers: 70067621001 (Moderna), 022B21A (Catalent)
Drug Substance Manufacturer: Moderna, Norwood, MA
Drug Substance Lot Number: 5007521045

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Document Approvals

Approved Date:

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