



CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60039
Manufacturer Name:	Catalent	Container/Closure:	10R Velocity Glass Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	047D21		
Moderna Lot Number:	6003921002	Specification:	SPC-1366
Date of Manufacture:	30Apr2021	Expiry Date:	30Nov2021

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)	(b) (4)
Identity	SOP-1032	Identity		
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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CERTIFICATE OF ANALYSIS

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Product Attribute	Method	Parameter	Specification	Result
Lipid Content		DSPC	(b) (4)	
		PEG-DMG		
		SM102		
Lipid Impurities		Cholesterol		
		DSPC		
		PEG-DMG		
		%Area 1		
		%Area 2		
		%Area 3		
		%Area 4		
		%Area 5		
		%Area 6		
		Particulate Matter		
RRT 2				
RRT 3				
RRT 4				
RRT 5				
RRT 6				
% Total Impurities				
		≥ 10 µm particles per container		
		≥ 25 µm particles per container		
Container Content	SOP-1229	Container Content	Syringe/Needle Option A: 15 doses of 0.5 mL from 1 vial Option B: 13 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: 7007621077 (Moderna), 047D21A (Catalent)
Drug Substance Manufacturer: Moderna, Norwood, MA
Drug Substance Lot Number: 5007521181

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Generated By: Steven Anderson

Document Number: VV-QUAL-005455 eDMS Version: 1.0 Page 2 of 3

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Document Approvals
Approved Date: 24 May 2021

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 24-May-2021 16:34:08 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 24-May-2021 17:18:39 GMT+0000