

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	85201
Manufacturer Name:	Moderna	Container/Closure:	2R Schott Vial, 13 mm Stopper, 13 mm PLASCAP 0.6 mL
Manufacturer Lot:	8520100103		
Moderna Lot Number:	8520100103	Specification:	SPC-0948
Date of Manufacture:	23Mar2020	Expiry Date:	23Mar2021

Product Attribute	Method	Parameter	Specification	Result
8410000103 - nCoV 2019 MPI-FPI				
Residual DNA template	SOP-0491	Residual DNA Template	(b) (4)	
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Pre-Main Peak Area		
		Main Peak Area		
8520100103 - 85201 mRNA-1273 nCoV DP				
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-0235	Concentration	(b) (4)	
Identity	SOP-0492	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0973	Result		

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Page 1 of 3

Generated Date: 01-Dec-2020

Document Number: VV-QUAL-002970 eDMS Version: 2.0 Page 1 of 4
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FDA-CBER-2022-1614-3815282



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Product Attribute	Method	Parameter	Specification	Result
pH	SOP-0288	pH	(b) (4)	
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Content		SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		

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Page 2 of 3

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Product Attribute	Method	Parameter	Specification	Result
		RRT 2	(b) (4)	
		RRT 3		
		RRT 4		
		% Total Impurities		
Particulate Matter	SOP-0509	10 µm particles per container		
		25 µm particles per container		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: No

Revision History:

- 1.0 - Original
- 2.0 - Updated polydispersity reported result (rounded from 0.1195 to 0.1)
 - Corrected Particulate Matter acceptance criteria
 - Corrected lipid impurity result from 0.8% to < LOQ
- 3.0- Extend expiry from 23Sep2020 (6M) to 23Mar2021 (12M) from DOM. Reference QC-OTH-0221.

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Page 3 of 3

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Document Approvals
Approved Date: 03 Dec 2020

Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Control Approval 01-Dec-2020 17:44:40 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 03-Dec-2020 03:04:24 GMT+0000