



1 Moderna Way • Norwood, MA 02062
phone 617-714-6500 • fax 617-583-1998

CERTIFICATE OF ANALYSIS

Product Description: mRNA-1273 Drug Product

Moderna Part #: 85201

Manufacturer Name: Moderna

Container/Closure: 2R Schott Vial, 13mm Stopper
13mm PLASCAP

Manufacturer Lot #: 8520100101

Moderna Lot #: 8520100101

Product Specification #: SPC-0948

Date of Manufacture: 07Feb2020

Expiry Date: 07Aug2020

Product Attribute	Method	Parameter	Specification	Result
mRNA-1273 mRNA Product Intermediate (MPI)				
Residual DNA template	qPCR Moderna SOP-0491	% w/w	(b) (4)	
% 5' Capped	RP-HPLC Moderna SOP-0467	% Cap1		
% Poly A Tailed RNA (% Tailless RNA)	RP-HPLC Moderna SOP-0291	% area		
mRNA-1273 Drug Product – Final Vial				
Appearance	Visual Moderna SOP-0278	Visual	White to off-white dispersion. May contain visible, white or translucent product-related particulates	White to off-white dispersion Essentially free of particulates
Total RNA content	Anion Exchange-HPLC Moderna SOP-0235	mg/mL	(b) (4)	
Identity	Reverse Transcription Sanger Sequencing Moderna SOP-0492	Identity		
Purity	RP-HPLC Moderna SOP-0383	% area		
Product-related Impurities	RP-HPLC Moderna SOP-0383	% area		
% RNA Encapsulation	(b) (4) Moderna SOP-0298	% encapsulation		
pH	USP <791> Moderna SOP-0288	pH		
Osmolality	USP <785> Freezing point depression Moderna SOP-0279	mOsm/kg		

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Particle Size	Dynamic Light Scattering Moderna SOP-0107	nm	(b) (4)	
Polydispersity	Dynamic Light Scattering Moderna SOP-0107	Polydispersity Index		
Lipid Identification SM-102 Cholesterol DSPC PEG2000-DMG	UPLC-CAD Moderna SOP-0502	Identity		
Lipid Content SM-102 Cholesterol DSPC PEG2000-DMG	UPLC-CAD Moderna SOP-0502	mg/mL		
Lipid Impurities	UPLC-CAD Moderna SOP-0502	% area		
Particulate Matter ≥ 25 µm ≥ 10 µm	USP <788> Method 2 Moderna SOP-0509	Particles per Container		
Bacterial Endotoxins	USP <85>, EP 2.6.14 Moderna SOP-0352	EU/mL		
Sterility	USP <71>, EP 2.6.1 Moderna SOP-0378	Sterility		

The material meets specification¹: Yes ☒ No ☐

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Product Attribute	Method	Parameter	Specification	Result
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Revision History:

1.0 – Original

2.0 – Removed “Interim” from title; added USP <71> sterility test result (SOP-0378)

Department

Signature

Date

(b) (6)

QC Review:

21 FEB 2020

QA Review:

21 FEB 2020

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