

cc: STN: xxxxx_0 / xxx /DP
Lot Number:
Licensed Name of Product: COVID-19
VaccineTrade Name:

Reason for Submission

☒ For Release
☐ For Surveillance
☐ For Licensing ActionSTN:
☐ Corrected Protocol

Lot Release Protocol

Manufacturer Name/Address:

STN:

Manufacturer Address:

Trade name:

Date of Manufacturing: 00/00/0000

Expiration Date: 00/00/0000

Label Strength: 00%

Source Material:

Processing Method:

Stabilizer: _____
 Manufacturer / Lot Number

Other:

Reprocessing/Heating:

Fill Information

Filling Date: 00/00/0000

Location:

Total Volume: 000 mL

Volume per Vial: 000 mL

Number of Vials filled: 0000

Number of Rejected Vials: 0000

Recommended Reconstitution Volume:

Storage Temperature:

All tests conducted on this lot are reported and pass specifications as required.

Signature:

Date:

Printed name: _____

Title: Authorized Official

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

Genealogy of the Lot

(b) (4)



ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

(b) (4)

1. Manufacture of CX-024414 mRNA [complete below or COA attached]

Date of Manufacture: _____ Lot Number: _____
Final Volume: _____ Storage Temperature: _____

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Appearance	Visual SOP-0278	(b) (4)			
Identity	RT/Sanger sequencing SOP-1019	(b) (4)			
Total RNA content	UV, SOP-0995				
Purity	RP-IP- HPLC, SOP-1142				

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Product-related Impurities	RP-IP-HPLC SOP-1142	(b) (4)			
% 5' Capped	HPLC-UV SOP-0997				
% Poly A tailed RNA	RP-HPLC SOP-0994				
% Tailless RNA	RP-HPLC SOP-0994				
pH	USP <791> SOP-0288				
Bacterial Endotoxin	USP <85> Ph. Eur. 2.6.14 SOP-0352				
Bioburden	USP <61>, Ph. Eur. 2.6.12 SOP-0480				

Abbreviations: qPCR = quantitative polymerase chain reaction; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; HPLC-UV = high-performance liquid chromatography with ultraviolet detection; RTSS = reverse transcription Sanger sequencing; TAMC = total aerobic microbial count; TYMC = total combined yeasts and molds count; UV = ultraviolet; w/w = weight/weight

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

2. Manufacture of mRNA-1273 Drug Product (DP) [complete below or COA attached]

Date of Manufacture: _____

Lot Number: _____

Fill Volume: _____

Storage Temperature: _____

Number of Vials Filled: _____

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Appearance	Visual SOP-0278	White to off white dispersion. May contain visible white or translucent product related particulates.			
Identity	RT/Sanger Sequencing SOP-1032	(b) (4)			
Total RNA content	AEX-HPLC SOP-0999				
Purity Product-related Impurities	RP-IP-HPLC SOP-1142 RP-IP-HPLC SOP-1142				
% RNA Encapsulation	(b) (4) SOP-1000				
In Vitro Translation	In Vitro Translation / methionine labeling SOP-0937		Sample:		
			Positive Control:		
			Lot #:		
Particle Size Polydispersity	Dynamic Light Scattering SOP-0998				
Lipids Identification SM-102 Cholesterol DSPC PEG2000-DMG	HPLC-CAD SOP-1001				
Lipids content SM-102 Cholesterol DSPC PEG2000-DMG	HPLC-CAD SOP-1001				
Lipid impurity	HPLC-CAD SOP-1001				

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Particulate Matter ≥ 25 µm ≥ 10 µm	USP <788> Method 2 SOP-0509	(b) (4)			
Container Content	USP <697> SOP-1229(a)				
pH	USP<791> SOP-0288				
Osmolality	USP <785> Freezing Point Depression SOP-0279				
Bacterial Endotoxin ¹	USP <85> Ph. Eur. 2.6.14				
Sterility ²	USP <71> Ph. Eur. 2.6.1				

Abbreviations: AEX-HPLC = anion exchange high-performance liquid chromatography; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; DLS = dynamic light scattering; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; EU = endotoxin unit(s); (b) (4)

(b) (4); RP-HPLC = reverse-phase high-performance liquid chromatography; (b) (4)

RTSS = reverse transcription Sangar sequencing; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

(b) (4)

¹ Refer to Appendix 1

² Refer to Appendix 2

Appendix 1: Endotoxin Test Details

Limulus Amebocyte Lysate Test

Method ☐ (b) (4) ☐ (b) (4)

Test date _____

Name of Lysate Manufacturer _____

Lysate Lot number _____

Standard Curve Information

Endotoxin lot number _____

Endotoxin Mfr/Supplier _____

Standard Curve

	Standard Endotoxin Concentration IU/mL	Mean Onset Time (seconds)	CV%
1			
2			
3			
4			
5			
6			

Correlation coefficient (r): _____ Intercept: _____ Slope: _____

Product Test Summary

MVD _____

	Results IU/mL	Test Dilution	Mean Onset Time	CV%	% Spike Recovery
Beginning					
Middle					
End					

Results (IU/mL): _____ Specifications: _____

Calculations or additional comments _____

Appendix 2: Sterility Test Details:

SOP number: _____

On Test Date	Medium/Temperature	Number of vials tested	Off Test Date

Result:

Specification: