

mRNA-1273 Drug Product Certificates of Analysis Attachment

Contents:

Clinical Trial Materials:

Scale A 3,000 Multiple-Dose Vial Lots (ModernaTX, Inc.):

- **6007520001** (GMP)
- **6007520002** (GMP)
- **6007520003** (GMP)
- **6007520004** (GMP)
- **6007520005** (GMP)
- **6007520006** (GMP)
- **6007520007** (GMP)
- **6007520008** (GMP)

Emergency Use Authorization Materials:

Scale A 10,000 Multiple-Dose Vial Lots (Catalent):

- **6007320001** (PPQ)
- **6007320002** (PPQ)
- **6007320003** (PPQ)
- **6007320004** (GMP)

Scale B 150,000 Multiple-Dose Vial Lots (Catalent):

- **6007320005** (PPQ)
- **6007920001** (LDP: **7006520006**) (PPQ)
- **6007920002** (LDP: **7006520007**) (PPQ)

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320001 (Labeled Drug Product)		
Moderna Lot Number:	6007520001	Specification:	SPC-1063
Date of Manufacture:	28May2020	Expiry Date:	28Aug2020

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Generated Date: 19-Jun-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320001 (Labeled Drug Product)		
Moderna Lot Number:	6007520001	Specification:	SPC-1063
Date of Manufacture:	28May2020	Expiry Date:	28Aug2020

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		
		% Area 5		
		% Area 6		
		% Area 7		
		% Area 8		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320001 (Labeled Drug Product)		
Moderna Lot Number:	6007520001	Specification:	SPC-1063
Date of Manufacture:	28May2020	Expiry Date:	28Aug2020

Product Attribute	Method	Parameter	Specification	Result
		RRT 5	(b) (4)	
		RRT 6		
		RRT 7		
		RRT 8		
		% Total Impurities		
Particulate Matter	SOP-0509	10 µM particles per container		
		25 µM particles per container		
Container Content	SOP-0950			
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

- 1.0 - Original
- 2.0 - Added Labeled Drug Product part number (7006320001) to CofA header

Document Approvals
Approved Date: 19 Jun 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 19-Jun-2020 14:45:06 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 19-Jun-2020 15:27:39 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320002 (Labeled Drug Product)		
Moderna Lot Number:	6007520002	Specification:	SPC-1063
Date of Manufacture:	02Jun2020	Expiry Date:	02Dec2020

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320002 (Labeled Drug Product)		
Moderna Lot Number:	6007520002	Specification:	SPC-1063
Date of Manufacture:	02Jun2020	Expiry Date:	02Dec2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		DSPC	(b) (4)	
		PEG-DMG		
		SM102		
		Cholesterol		
Lipid Impurities		DSPC		
		PEG-DMG		
		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		% Area 5		
		% Area 6		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		RRT 5		
		RRT 6		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320002 (Labeled Drug Product)		
Moderna Lot Number:	6007520002	Specification:	SPC-1063
Date of Manufacture:	02Jun2020	Expiry Date:	02Dec2020

Product Attribute	Method	Parameter	Specification	Result
		% Total Impurities	(b) (4)	
Particulate Matter	SOP-0509	10 µM particles per container		
		25 µM particles per container		
Container Content	SOP-0950	Container Content		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

- 1.0 - Original
- 2.0 - Expiry date updated from 02Sep2020 to 02Dec2020

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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 14-Aug-2020 15:21:18 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320003 (Labeled Drug Product)		
Moderna Lot Number:	6007520003	Specification:	SPC-1063
Date of Manufacture:	04Jun2020	Expiry Date:	04Dec2020

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320003 (Labeled Drug Product)		
Moderna Lot Number:	6007520003	Specification:	SPC-1063
Date of Manufacture:	04Jun2020	Expiry Date:	04Dec2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		DSPC	(b) (4)	
		PEG-DMG		
		SM102		
		Cholesterol		
Lipid Impurities		DSPC		
		PEG-DMG		
		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		% Area 5		
		% Area 6		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		RRT 5		
		RRT 6		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320003 (Labeled Drug Product)		
Moderna Lot Number:	6007520003	Specification:	SPC-1063
Date of Manufacture:	04Jun2020	Expiry Date:	04Dec2020

Product Attribute	Method	Parameter	Specification	Result
		% Total Impurities	(b) (4)	
Particulate Matter	SOP-0509	10 µM particles per container		
		25 µM particles per container		
Container Content	SOP-0950	Container Content		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

- 1.0 - Original
- 2.0 - Expiry updated from 04Sep2020 to 04Dec2020

Document Approvals
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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320004 (Labeled Drug Product)		
Moderna Lot Number:	6007520004	Specification:	SPC-1063
Date of Manufacture:	25Jun2020	Expiry Date:	25Dec2020

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320004 (Labeled Drug Product)		
Moderna Lot Number:	6007520004	Specification:	SPC-1063
Date of Manufacture:	25Jun2020	Expiry Date:	25Dec2020

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µM particles per container		
		25 µM particles per container		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320004 (Labeled Drug Product)		
Moderna Lot Number:	6007520004	Specification:	SPC-1063
Date of Manufacture:	25Jun2020	Expiry Date:	25Dec2020

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	(b) (4)	
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

- 1.0 - Original
- 2.0 - Batch Date corrected from 26Jun2020 to 25Jun2020. Expiry date corrected to 26Sep2020 to 25Sep2020
- 3.0 - Expiry date updated from 25Sep2020 to 25Dec2020

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QA Approval Verdict: Approved	(b) (6) @modernatx.com) Quality Assurance Approval 14-Aug-2020 15:02:32 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320005 (Labeled Drug Product)		
Moderna Lot Number:	6007520005	Specification:	SPC-1063
Date of Manufacture:	30Jun2020	Expiry Date:	30Dec2020

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Generated Date: 05-Aug-2020

FDA-CBER-2022-1614-4622433

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320005 (Labeled Drug Product)		
Moderna Lot Number:	6007520005	Specification:	SPC-1063
Date of Manufacture:	30Jun2020	Expiry Date:	30Dec2020

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µM particles per container		
		25 µM particles per container		

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Generated Date: 05-Aug-2020

FDA-CBER-2022-1614-4622434

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320005 (Labeled Drug Product)		
Moderna Lot Number:	6007520005	Specification:	SPC-1063
Date of Manufacture:	30Jun2020	Expiry Date:	30Dec2020

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	(b) (4)	
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

2.0 - Corrected Batch Date from 01Jul2020 to 30Jun2020 and expiry date from 01Jan2021 to 30Dec2020.

Document Approvals
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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 05-Aug-2020 17:46:53 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320006 (Labeled Drug Product)		
Moderna Lot Number:	6007520006	Specification:	SPC-1063
Date of Manufacture:	08Jul2020	Expiry Date:	08Jan2021

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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FDA-CBER-2022-1614-4622437

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320006 (Labeled Drug Product)		
Moderna Lot Number:	6007520006	Specification:	SPC-1063
Date of Manufacture:	08Jul2020	Expiry Date:	08Jan2021

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µM particles per container		
		25 µM particles per container		

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320006 (Labeled Drug Product)		
Moderna Lot Number:	6007520006	Specification:	SPC-1063
Date of Manufacture:	08Jul2020	Expiry Date:	08Jan2021

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	(b) (4)	
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

2.0 - Corrected SOP-0509 Lipid Analysis RRT labeling. No changes to reported results, RRT incorrectly started at RRT2 instead of RRT1 for impurity tracking in version 1.0.

Corrected batch date from 07Jul2021 to 08Jul2020 and expiry date from 07Jan2021 to 08Jan2021

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QA Approval Verdict: Approved	(b) (6) @modernatx.com) Quality Assurance Approval 05-Aug-2020 19:42:07 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320007 (Labeled Drug Product)		
Moderna Lot Number:	6007520007	Specification:	SPC-1063
Date of Manufacture:	09Jul2020	Expiry Date:	09Jan2021

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Generated Date: 14-Aug-2020

FDA-CBER-2022-1614-4622441

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320007 (Labeled Drug Product)		
Moderna Lot Number:	6007520007	Specification:	SPC-1063
Date of Manufacture:	09Jul2020	Expiry Date:	09Jan2021

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		% Total Impurities		
Particulate Matter	SOP-0509	10 µM particles per container		
		25 µM particles per container		

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Generated Date: 14-Aug-2020

FDA-CBER-2022-1614-4622442

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320007 (Labeled Drug Product)		
Moderna Lot Number:	6007520007	Specification:	SPC-1063
Date of Manufacture:	09Jul2020	Expiry Date:	09Jan2021

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	(b) (4)	
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals
Approved Date: 14 Aug 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 14-Aug-2020 19:12:03 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 14-Aug-2020 19:38:39 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320008 (Labeled Drug Product)		
Moderna Lot Number:	6007520008	Specification:	SPC-1063
Date of Manufacture:	21Aug2020	Expiry Date:	21Feb2021

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-0235	Concentration	(b) (4)	
Identity	SOP-0544	Identity		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Page 1 of 3

Generated Date: 03-Oct-2020

FDA-CBER-2022-1614-4622445

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320008 (Labeled Drug Product)		
Moderna Lot Number:	6007520008	Specification:	SPC-1063
Date of Manufacture:	21Aug2020	Expiry Date:	21Feb2021

Product Attribute	Method	Parameter	Specification	Result
		DSPC	(b) (4)	
		PEG-DMG		
Lipid Content		SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		RRT 1		
		RRT 2		
		RRT 3		
		% Total Impurities		
Particulate Matter	SOP-0509	10 µM particles per container		
		25 µM particles per container		
Container Content	SOP-0950	Container Content		

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Page 2 of 3

Generated Date: 03-Oct-2020

FDA-CBER-2022-1614-4622446

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60075
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Plascap
Manufacturer Lot:	7006320008 (Labeled Drug Product)		
Moderna Lot Number:	6007520008	Specification:	SPC-1063
Date of Manufacture:	21Aug2020	Expiry Date:	21Feb2021

Product Attribute	Method	Parameter	Specification	Result
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

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Page 3 of 3

Generated Date: 03-Oct-2020

FDA-CBER-2022-1614-4622447

Document Approvals
Approved Date: 07 Oct 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 05-Oct-2020 13:46:49 GMT+0000
QA Approval Verdict: Approved	(b) (6) @modernatx.com) Quality Assurance Approval 06-Oct-2020 23:45:24 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	057G20		
Moderna Lot Number:	6007320001	Specification:	SPC-1128
Date of Manufacture:	30Jul2020	Expiry Date:	30Jan2021

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-0235	Concentration	(b) (4) (Target: 0.20 mg/mL)	
Identity	SOP-0544	Identity	(b) (4)	
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Generated Date: 11-Sep-2020

FDA-CBER-2022-1614-4622449
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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	057G20		
Moderna Lot Number:	6007320001	Specification:	SPC-1128
Date of Manufacture:	30Jul2020	Expiry Date:	30Jan2021

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µM particles per container		
		25 µM particles per container		

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Page 2 of 3

Generated Date: 11-Sep-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	057G20		
Moderna Lot Number:	6007320001	Specification:	SPC-1128
Date of Manufacture:	30Jul2020	Expiry Date:	30Jan2021

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one vial)	(b) (4)
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

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Page 3 of 3

Generated Date: 11-Sep-2020

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Document Approvals
Approved Date: 15 Sep 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 11-Sep-2020 15:37:51 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 15-Sep-2020 14:17:33 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	062G20		
Moderna Lot Number:	6007320002	Specification:	SPC-1128
Date of Manufacture:	06Aug2020	Expiry Date:	06Feb2021

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-0235	Concentration	(b) (4) (Target: 0.20 mg/mL)	
Identity	SOP-0544	Identity	(b) (4)	
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result	(b) (4)	
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102	(b) (4)	
		Cholesterol		

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Generated Date: 11-Sep-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	062G20		
Moderna Lot Number:	6007320002	Specification:	SPC-1128
Date of Manufacture:	06Aug2020	Expiry Date:	06Feb2021

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µM particles per container		
		25 µM particles per container		

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Generated Date: 11-Sep-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	062G20		
Moderna Lot Number:	6007320002	Specification:	SPC-1128
Date of Manufacture:	06Aug2020	Expiry Date:	06Feb2021

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one vial)	(b) (4)
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

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Generated Date: 11-Sep-2020

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Document Approvals
Approved Date: 16 Sep 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 11-Sep-2020 17:44:20 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 15-Sep-2020 17:14:58 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	001H20		
Moderna Lot Number:	6007320003	Specification:	SPC-1128
Date of Manufacture:	11Aug2020	Expiry Date:	11Feb2021

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-0235	Concentration	(b) (4) (Target: 0.20 mg/mL)	
Identity	SOP-0544	Identity	(b) (4)	
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Generated Date: 11-Sep-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	001H20		
Moderna Lot Number:	6007320003	Specification:	SPC-1128
Date of Manufacture:	11Aug2020	Expiry Date:	11Feb2021

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µM particles per container		
		25 µM particles per container		

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Generated Date: 11-Sep-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Moderna	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	001H20		
Moderna Lot Number:	6007320003	Specification:	SPC-1128
Date of Manufacture:	11Aug2020	Expiry Date:	11Feb2021

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one vial)	(b) (4)
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins	(b) (4)	
Sterility	SOP-0378	Sterility		

This material meets specification: Yes

Revision History:

1.0 - Original

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Generated By: Steven Anderson

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Generated Date: 11-Sep-2020

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Document Approvals
Approved Date: 16 Sep 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 13-Sep-2020 16:19:35 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 15-Sep-2020 17:18:55 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	032H20		
Moderna Lot Number:	6007320004	Specification:	SPC-1128
Date of Manufacture:	13Sep2020	Expiry Date:	13Mar2021

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-0235	Concentration	(b) (4) (Target: 0.20 mg/mL)	
Identity	SOP-0544	Identity	(b) (4)	
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation (Potency)	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Page 1 of 3

Generated Date: 13-Nov-2020

FDA-CBER-2022-1614-4622461

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	032H20		
Moderna Lot Number:	6007320004	Specification:	SPC-1128
Date of Manufacture:	13Sep2020	Expiry Date:	13Mar2021

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		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
Particulate Matter	SOP-0509	% Total Impurities		
		10 µm particles per container		
		25 µm particles per container		

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Generated Date: 13-Nov-2020

FDA-CBER-2022-1614-4622462

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	032H20		
Moderna Lot Number:	6007320004	Specification:	SPC-1128
Date of Manufacture:	13Sep2020	Expiry Date:	13Mar2021

Product Attribute	Method	Parameter	Specification	Result
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one 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
2.0 - Revised expiration date to 13Mar2021

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Generated By: Steven Anderson

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Generated Date: 13-Nov-2020

FDA-CBER-2022-1614-4622463

Document Approvals
Approved Date: 13 Nov 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 14-Nov-2020 00:15:44 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 14-Nov-2020 00:33:20 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	011J20		
Moderna Lot Number:	6007320005	Specification:	SPC-1128
Date of Manufacture:	11Oct2020	Expiry Date:	11Apr2021

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-0235	Concentration	(b) (4) (Target: 0.20 mg/mL)	
Identity	SOP-0544	Identity	(b) (4)	
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
% RNA Encapsulation	SOP-0298	% Encapsulation		
In vitro Translation	SOP-0937	Result		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		

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Generated Date: 13-Nov-2020

FDA-CBER-2022-1614-4622465

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	011J20		
Moderna Lot Number:	6007320005	Specification:	SPC-1128
Date of Manufacture:	11Oct2020	Expiry Date:	11Apr2021

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		
		% Area 5		
		% Area 6		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		RRT 5		
		RRT 6		

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Generated Date: 13-Nov-2020

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CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	60073
Manufacturer Name:	Catalent	Container/Closure:	10R Glass Vial, 20mm Stopper, 20mm Cap
Manufacturer Lot:	011J20		
Moderna Lot Number:	6007320005	Specification:	SPC-1128
Date of Manufacture:	11Oct2020	Expiry Date:	11Apr2021

Product Attribute	Method	Parameter	Specification	Result
Particulate Matter	SOP-0509	% Total Impurities	(b) (4)	
		10 µm particles per container		
		25 µm particles per container		
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one 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
2.0 - Revised expiry to 11Apr2021

Document Approvals
Approved Date: 13 Nov 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 14-Nov-2020 00:16:33 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 14-Nov-2020 00:32:50 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 RTU Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20		
Moderna Lot Number:	7006520006	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25May2021

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	Concentration	(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	(b) (4)	
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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Generated Date: 07-Dec-2020

FDA-CBER-2022-1614-4622469

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 RTU Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20		
Moderna Lot Number:	7006520006	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25May2021

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		
		% Area 5		
		% Area 6		
		% Area 7		
		% Area 8		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		

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FDA-CBER-2022-1614-4622470

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 RTU Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20		
Moderna Lot Number:	7006520006	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25May2021

Product Attribute	Method	Parameter	Specification	Result
Particulate Matter	SOP-0509	RRT 5	(b) (4)	
		RRT 6		
		RRT 7		
		% Total Impurities		
		10 µm particles per container		
		25 µm particles per container		
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one 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 Certificate of Analysis, Unlabeled Drug Product Lot: 6007920001

Document Approvals
Approved Date: 07 Dec 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 07-Dec-2020 15:14:07 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 07-Dec-2020 16:18:40 GMT+0000

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 RTU Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20-2		
Moderna Lot Number:	7006520007	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25Feb2021

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	Concentration	(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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Generated Date: 07-Dec-2020

FDA-CBER-2022-1614-4622473

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 RTU Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20-2		
Moderna Lot Number:	7006520007	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25Feb2021

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		
		% Area 5		
		% Area 6		
		% Area 7		
		% Area 8		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		

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FDA-CBER-2022-1614-4622474

CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	70065
Manufacturer Name:	Catalent	Container/Closure:	10R SiO2 RTU Vial, 20 mm Stopper, 20 mm Cap
Manufacturer Lot:	025J20-2		
Moderna Lot Number:	7006520007	Specification:	SPC-1128
Date of Manufacture:	25Oct2020	Expiry Date:	25Feb2021

Product Attribute	Method	Parameter	Specification	Result
Particulate Matter	SOP-0509	RRT 5	(b) (4)	
		RRT 6		
		RRT 7		
		RRT 8		
		% Total Impurities		
		10 µm particles per container		
		25 µm particles per container		
Container Content	SOP-0950	Container Content	>= 5.0 mL (>=10 doses of 0.5 mL from one 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 Certificate of Analysis, Unlabeled Drug Product Lot: 6007920002

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FDA-CBER-2022-1614-4622475

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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 07-Dec-2020 16:18:11 GMT+0000