

### **3.2.P.5.4 BATCH ANALYSES**

Batch analysis data is generated for GMP mRNA-1273 Drug Product according to an approved specification as presented in [Table 1](#) and [Table 2](#). Refer to [Section 3.2.P.2.3.7.4](#) for additional details concerning specification changes and [Section 3.2.P.2.3.7.5](#) for additional details concerning analytical procedure changes. As described in [Section 3.2.P.5.3](#), analytical method validation is complete. Moving forward, mRNA-1273 Drug Product will be tested in accordance with the validated methods.

Batch Analysis data for clinical trial materials is provided in [Section 3.2.P.5.4.1](#) and batch analysis data for Emergency Use Authorization material is provided in [Section 3.2.P.5.4.2](#).

The Certificates of analyses are provided as an attachment in this section ([CoAs mRNA-1273 Drug Product Lots](#)).

### 3.2.P.5.4.1 Batch Analysis Data for Clinical Trial Material

**Table 1: Batch Analysis Data for mRNA-1273 Drug Product (Scale A)**

GMP mRNA-1273 Drug Product Lot Number		6007520001	6007520002	6007520003	6007520004	6007520005	6007520006	6007520007	6007520008
Manufacturer Lot Number									
Date of Manufacture		28May2020	02Jun2020	04Jun2020	25Jun2020	30Jun2020	08Jul2020	09Jul2020	21Aug2020
Manufacturing Location		ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.
Purpose		Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot
Scale		3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)
Yield (Vials passing Visual Inspection)		(b) (4)							
Release Specification		SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 2	SPC-1063, Version 2	SPC-1063, Version 2
Test	Acceptance Criteria	Results							
Appearance (SOP-0278)	White to off-white dispersion. May contain visible, white or translucent product-related particulates	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.
RNA content by AEX-HPLC (SOP-0235)	(b) (4)	(b) (4)							
Identity by Rev Transcription/Sanger Sequencing (SOP-0544)	(b) (4)	(b) (4)							
Purity by RP-HPLC (SOP-0383)	(b) (4)	(b) (4)			N/A	N/A	N/A	N/A	N/A
		N/A	N/A	N/A	(b) (4)				
Product-related impurities by RP-HPLC (SOP-0383)	(b) (4)	(b) (4)							
% RNA encapsulation by (b) (4) (SOP-0298)									
In vitro Translation (SOP-0937)									
pH (SOP-0288)									
Osmolality (SOP-0279)									
Particle size by Dynamic Light Scattering (SOP-0107)									
Polydispersity by Dynamic Light Scattering (SOP-0107)	Report results				(b) (4)	N/A	N/A	N/A	N/A
	(b) (4)	N/A	N/A	N/A	N/A	(b) (4)			

GMP mRNA-1273 Drug Product Lot Number		6007520001	6007520002	6007520003	6007520004	6007520005	6007520006	6007520007	6007520008
Manufacturer Lot Number									
Date of Manufacture		28May2020	02Jun2020	04Jun2020	25Jun2020	30Jun2020	08Jul2020	09Jul2020	21Aug2020
Manufacturing Location		ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.	ModernaTX, Inc.
Purpose		Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot	Phase 3/Clinical lot
Scale		3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)	3000 vial (Scale A)
Yield (Vials passing Visual Inspection)		(b) (4)							
Release Specification		SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 1	SPC-1063, Version 2	SPC-1063, Version 2	SPC-1063, Version 2
Test		Acceptance Criteria		Results					
Lipid identification by UPLC-CAD (SOP-0502)	SM-102	(b) (4)	(b) (4)						
	Cholesterol								
	DSPC								
	PEG2000-DMG								
Lipid content by UPLC-CAD (SOP-0502)	SM-102	(b) (4)	(b) (4)		(b) (4)				
	Cholesterol								
	DSPC		N/A		N/A	N/A	N/A	N/A	
	PEG2000-DMG		(b) (4)		(b) (4)				
Lipid impurities by UPLC-CAD (SOP-0502)		(b) (4)	(b) (4)		(b) (4)				
		(b) (4)	(b) (4)		(b) (4)				
Particulate matter (SOP-0509)		(b) (4)	(b) (4)						
Container content (SOP-0950)		(b) (4)	(b) (4)						
Bacterial endotoxin									
Sterility									

Abbreviations: N/A = specification is not applicable for product; kDa = kilodalton; RT = retention time; (b) (4)  
a) The stability Acceptance Criteria for %purity is (b) (4) as presented in [Section 3.2.P.8.3](#)

### 3.2.P.5.4.2 Batch Analysis Data for Emergency Use Authorization Material

**Table 2: Batch Analysis Data for mRNA-1273 Drug Product Scale A and Scale B PPQ and Post PPQ GMP lots**

GMP mRNA-1273 Drug Product Lot Number		6007320001	6007320002	6007320003	6007320004	6007320005	6007920001 (LDP: 7006520006)	6007920002 (LDP: 7006520007)
Manufacturer Lot Number		057G20	062G20	001H20	032H20	011J20	025J20	025J20-2
Date of Manufacture		30Jul2020	06Aug2020	11Aug2020	13Sep2020	11Oct2020	25 Oct 2020	25 Oct 2020
Manufacturing Location		Catalent	Catalent	Catalent	Catalent	Catalent	Catalent	
Purpose		PPQ lot	PPQ lot	PPQ lot	GMP lot	PPQ lot	PPQ lot <sup>(d)</sup>	
Scale		10000 vial (Scale A)	10000 vial (Scale A)	10000 vial (Scale A)	10000 vial (Scale A)	150000 vial (Scale B)	150000 vial (Scale B)	
Yield (Vials passing Visual Inspection)		(b) (4)						
Release Specification		SPC-1128, Version 1	SPC-1128, Version 1	SPC-1128, Version 1	SPC-1128, Version 1	SPC-1128, Version 2	SPC-1128, Version 3	
Test		Acceptance Criteria		Results				
Appearance (SOP-0278)	White to off-white dispersion. May contain visible, white or translucent product-related particulates	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.	White to off-white dispersion, essentially free of particulates.
RNA content by AEX-HPLC (SOP-0999)	(b) (4)	(b) (4)						
Identity by Rev Transcription/Sanger Sequencing (SOP-1032)		(b) (4)						
Purity by RP-HPLC (SOP-0996)		(b) (4)					(b) (4)	
Product-related impurities by RP-HPLC (SOP-0996)								
% RNA encapsulation								
by (b) (4) (SOP-0298)							N/A	N/A
by (b) (4) (SOP-1000)		N/A	N/A	N/A	N/A	N/A	(b) (4)	
In vitro Translation (SOP-0937)		(b) (4)						
pH (SOP-0288)								
Osmolality (SOP-0279)								
Particle size by Dynamic Light Scattering (SOP-0998)								
Polydispersity by Dynamic Light Scattering (SOP-0998)								

GMP mRNA-1273 Drug Product Lot Number		6007320001	6007320002	6007320003	6007320004	6007320005	6007920001 (LDP: 7006520006)	6007920002 (LDP: 7006520007)
Manufacturer Lot Number		057G20	062G20	001H20	032H20	011J20	025J20	025J20-2
Date of Manufacture		30Jul2020	06Aug2020	11Aug2020	13Sep2020	11Oct2020	25 Oct 2020	25 Oct 2020
Manufacturing Location		Catalent	Catalent	Catalent	Catalent	Catalent	Catalent	
Purpose		PPQ lot	PPQ lot	PPQ lot	GMP lot	PPQ lot	PPQ lot <sup>(d)</sup>	
Scale		10000 vial (Scale A)	10000 vial (Scale A)	10000 vial (Scale A)	10000 vial (Scale A)	150000 vial (Scale B)	150000 vial (Scale B)	
Yield (Vials passing Visual Inspection)		(b) (4)						
Release Specification		SPC-1128, Version 1	SPC-1128, Version 1	SPC-1128, Version 1	SPC-1128, Version 1	SPC-1128, Version 2	SPC-1128, Version 3	
Test		Acceptance Criteria						
Lipid identification by UPLC-CAD (SOP-1001)	SM-102	(b) (4)						
	Cholesterol							
	DSPC							
	PEG2000-DMG							
Lipid content by UPLC-CAD (SOP-1001)	SM-102	(b) (4)					(b) (4)	
	Cholesterol							
	DSPC							
	PEG2000-DMG							
Lipid impurities by UPLC-CAD (SOP-1001)		(b) (4)						
		(b) (4)						
Particulate matter (SOP-0509)		(b) (4)						
Container content (SOP-0950)								
Bacterial endotoxin								
Sterility								

Abbreviations: N/A = specification is not applicable for product; kDa = kilodalton; RT = retention time; (b) (4); PPQ = Process Performance Qualification; LDP = Labeled Drug Product

a) (b) (4)

b) (b) (4)

c) (b) (4)

d) (b) (4)

e) (b) (4)

f) The stability Acceptance Criteria for %purity is (b) (4) as presented in [Section 3.2.P.8.3](#)