

3.2.S.4.4 BATCH ANALYSES

CX-024414 GMP lots are intended for further manufacturing into mRNA-1273 Drug Product GMP lots. Batch analysis date is generated for CX-024414 according to an approved specification as presented in [Table 1](#) and [Table 2](#). Refer to [Section 3.2.S.2.6.3 {CX-024414}](#) for additional details concerning specification changes and [Section 3.2.S.2.6.4 {CX-024414}](#) for additional details concerning analytical procedure changes.

The certificates of analyses are provided as an attachment in this section ([CofAs CX-024414 Lots](#)).

Table 1: Batch Analyses Data for GMP CX-024414 Scale A (10 L IVT) and Initial Scale B (20 L IVT) Lots

CX-024414 GMP Lot Number		4007220001	4007220002	4007220003	4007220004	4007220005	4007520001	4007520002	4007520003	4007520004
							Lonza Lot 918988	Lonza Lot 922693	Lonza Lot 928769	Lonza Lot 930143
Date of Manufacture		03Apr2020	04May2020	20May2020	04Jun2020	18Jun2020	28Jul2020	12Aug2020	25Aug2020	31Aug2020
Manufacturing Location		ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	Lonza Biologics, Inc. (Portsmouth, NH)	Lonza Biologics, Inc. (Portsmouth, NH)	Lonza Biologics, Inc. (Portsmouth, NH)	Lonza Biologics, Inc. (Portsmouth, NH)
Purpose		Phase 3 IND	Phase 3 IND	Phase 3 IND 10 L IVT Scale A PPQ	Phase 3 IND 10 L IVT Scale A PPQ	Phase 3 IND 10 L IVT Scale A PPQ	20 L IVT GMP	20 L IVT Initial Scale B PPQ	20 L IVT Initial Scale B PPQ	20 L IVT Initial Scale B PPQ
IVT Scale		10 L	10 L	10 L	10 L	10 L	20 L	20 L	20 L	20 L
Yield (grams)		CCI								
Release Specification		SPC-1995, Version 1	SPC-1995, Version 1	SPC-1995, Version 1	SPC-1995, Version 1	SPC-1995, Version 1	SPC-1118 Version 1	SPC-1118 Version 1	SPC-1118 Version 1	SPC-1118 Version 1
Test	Acceptance Criteria	Results								
Appearance (SOP-0278)	Clear, colorless solution	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
	Essentially free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates
Identity by Reverse Transcription/Sanger Sequencing (SOP-0492)	Sequence matches 100% description of coding region	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Total RNA content by UV (SOP-0249)	CCI									
Purity by RP-HPLC (SOP-0321)										
Product-related impurities by RP-HPLC (SOP-0321)										
% 5' Capped by RP-UPLC-UV (SOP-0467)										
% PolyA tailed RNA (% Tailless RNA) by RP-HPLC (SOP-0291)										
Residual DNA template by qPCR (SOP-0491)										
pH (SOP-0288)										
Bacterial endotoxin USP <85>, Ph. Eur. 2.6.14 (SOP-0352)										
Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480)										

LOQ = Limit of Quantitation

a) LOQ is CCI

b) With the implementation of the parameter change as described in Table 4, Section 3.2.S.2.6 {CX-024414}, an expected increase in productivity was achieved and the resultant yield of purified CX-024414 was increased by CCI

c) Bioburden tested using CCI per Deviation QE-002523.

Table 2: Batch Analyses Data for GMP CX-024414 Final Scale B (60L IVT) Lots

CX-024414 GMP Lot Number		4007420001	4007420002	4007420003	4007420010	4007420004
					Lonza Lot 943122	
Date of Manufacture		20Sep2020	03Oct2020	19Oct2020	27Oct2020	31Oct2020
Manufacturing Location		ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	Lonza Biologics, Inc. (Portsmouth, NH)	ModernaTX, Inc. Norwood, MA
Purpose		60 L IVT GMP	60 L IVT GMP	60 L IVT PPQ	60 L IVT GMP	60 L IVT PPQ
IVT Scale		60 L	60 L	60 L	60 L	60 L
Yield (grams)		CCI				
Release Specification						
		SPC-1149 Version 1	SPC-1149 Version 1	SPC-1149 Version 1	SPC-1149 Version 2	SPC-1149 Version 2
Test	Acceptance Criteria	Results				
Appearance (SOP-0278)	Clear, colorless solution	Conforms	Conforms	Conforms	Conforms	Conforms
	Essentially free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates	Free of visible particulates
Identity by Reverse Transcription/Sanger Sequencing (SOP-0492)	Sequence matches 100% description of coding region	Conforms	Conforms	Conforms	Conforms	Conforms
Total RNA content by UV (SOP-0249)	CCI					
Purity by RP-HPLC (SOP-0321)						
Product-related impurities by RP-HPLC (SOP-0321)						
% 5' Capped by RP-UPLC-UV (SOP-0467)						
% PolyA tailed RNA (% Tailless RNA) by RP-HPLC (SOP-0291)						
Residual DNA template by qPCR (SOP-0491)						
pH (SOP-0288)						
Bacterial endotoxin USP <85>, Ph. Eur. 2.6.14 (SOP-0352)						
Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480)						

LOQ = Limit of Quantitation
a) LOQ is CCI