

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](#). Refer to [Section 3.2.S.2.6.3 {CX-024414}](#) for additional details concerning specification changes and [REDACTED] for additional details concerning analytical procedure changes. As described in [Section 3.2.S.4.3 {CX-024414}](#), analytical method validation is complete. Moving forward, CX-024414 will be tested in accordance with the validated methods.

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 Lots

CX-024414 GMP Lot Number		4007220001	4007220002	4007220003	4007220004	4007220005	4007520001	4007520002	4007520003	4007520004	4007420001	4007420002
Date of Manufacture		03Apr2020	04May2020	20May2020	04Jun2020	18Jun2020	Lonza Lot 918988	Lonza Lot 922693	Lonza Lot 928769	Lonza Lot 930143	20Sep2020	03Oct2020
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)	ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA
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	60 L IVT GMP	60 L IVT GMP
IVT Scale		10 L	10 L	10 L	10 L	10 L	20 L	20 L	20 L	20 L	60 L	60 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	SPC-1149 Version 1	SPC-1149 Version 1
Test	Acceptance Criteria	Results										
Appearance (SOP-0278)	Clear, colorless solution	Conforms	Conforms	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	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	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 [redacted]
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 [redacted]
c) Bioburden tested using [redacted] per Deviation QE-002523.