s generated for CX-024414 according to a

able 1 and Table 2. Refer to Section 3.2.5.2.6.3 (CX)

erning specification changes and Section 3.2.5.2.6.4 (CX-t)

oncerning analytical procedure changes.

s of analyses are provided as an attachment in this sects.

3-24414 Lots).

4-24414 Lots

1-24414 permeation 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 case. (CofAs CX-024414 Lots).

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

Date of Manufacture	CX-024414 GMP Lot Number		4007220001	4007220002	4007220003	4007220004	4007220005	4007520001	4007520002	4007520003	4007520004
ModernaTX, Inc. Noverous MA No			700/220001	700/220002	4007220003	700/220004	700/220003	Lonza Lot 918988	Lonza Lot 922693	Lonza Lot 928769	Lonza Lot 930143
Normond, MA	Date of Manufacture		03Apr2020	04May2020	20May2020	04Jun2020	18Jun2020	28Jul2020		25Aug2020	31Aug2020
Phase 3 ND	Manufacturing Location										Lonza Biologics, Inc (Portsmouth, NH)
No. 191. 1	Purpose		Phase 3 IND	Phase 3 IND	10 L IVT	10 L IVT	10 L IVT	20 L IVT GMP	20 L IVT Initial Scale B PPQ		20 L IVT Initial Scale B PPQ
Release Specification Test Acceptance Criferia Test Acceptance Criferia Clear, colorisos pulnos Essentially free of Candenus Conforms Confor	IVT Scale		10 L	10 L				20 L	20 L	20 L	20 L
Appearance Clear, colorises solution Conforms Co	Yield (grams)		CCI								
Appearance (SOP-4278) Clear, colordess solution Conforms Confor	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
Appenunce Sign Conference Sign	Test	Acceptance Criteria					Results	3			
Esternially free of yearble Pree of yearble	Ammaananaa	Clear, colorless solution	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Sequence anaches 100%	(SOP-0278)	Essentially free of visible particulates					Free of visible particulates				Free of visible particulates
by UV (SGOP-0239) Purity by RR-HPLC (SGOP-0221) Product-related impurities by RR-HPLC (SGOP-0321) % 5' Capped by RR-HPLC (SGOP-0321) % 5' Capped by RR-HPLC (SGOP-0321) % 5' Capped by RR-HPLC (SGOP-0321) SP PDA Variable RNA (% Tailless RNA) by RR-HPLC (SGOP-0291) Residual DNA template by spCR (SGOP-0291) Batternal endotoxin Batternal endotoxin USP +65-1, Ph. Eur. 2.6.14 (SGOP-0385) Batternal endotoxin USP +65-1, Ph. Eur. 2.6.12 (SGOP-0488) OQ = Limit of Quantitation	by Reverse Transcription/Sanger Sequencing (SOP-0492)	Sequence matches 100%									Conforms
SOP-0239		CCI									
Product-related impurities by RP-HPLC (SOP-0321) Product-related impurities by RP-HPLC (SOP-0321) % 5' Capped by RP-UPLC-UV (SOP-0347) % by RP-HPLC (SOP-0347) % by RP-HPLC (SOP-0347) Residual DNA template by ap-CR (SOP-0347) H (SOP-0347) Bacterial endotoxin (SSP-035) SSP-Br-Eur-2.6.14 (SOP-0352) Bioburden (ISP-036): Ph. Eur-2.6.12 (SOP-0348) Book of the soprement of counstantion OQ = Limit of Quantitation	(SOP-0249)										
(SOP-0321) Product-related impurities by RP-HPLC (SOP-0321) % **Capped by RP-HPLC-UV (SOP-0457) % Poly A tailed RNA (% Tailles RNA) by RP-HPLC (SOP-0491) Residual DNA template by gPCR (SOP-0491) PH (SOP-0288) Bacterial endoxin (SOP-0389) Buckerla endoxin (SOP-058) Ph Eur. 2.6.14 (SOP-0480) OQ = Limit of Quantitation OQ = Limit of Quantitation	by RP-HPLC										
by RP-HPLC (SOP-0421) % 5' Capped by RP-UPLC-UV (SOP-0467) % Polya tailed RNA (% Tailles RNA) by RP-HPLC (SOP-0491) Residual DNA template by qFCR (SOP-0491) pH (SOP-0491) Bacterial endotoxin USP-e8Ss, Ph. Eur. 2.6.14 (SOP-0480) OQ = Limit of Quantitation	(SOP-0321)										
% 5' Capped by RP-UPLC-UV (SOP-0467) % PolyA tailed RNA (% Tailles RNA) by RP-HPLC (SOP-0291) Residual DNA (emplate by qPCR (SOP-0991) pil (SOP-0998) Bacterial endotoxin USP-485, Ph. Eur. 2.6.14 (SOP-05P, Ph. Eur. 2.6.12 (SOP-05P) Bioburden USP-615, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation	Product-related impurities										
% 5' Capped by RP-UPLC-UV (SOP-0467) % Poly A tailed RNA (% Tailles RNA) by RP-HPLC (SOP-0491) Residual DNA template by qFCR (SOP-0491) pH (SOP-0491) Bacterial endotoxin USP-85S, Ph, Eur. 2.6.14 (SOP-0452) Bioburden USP-85S, Ph, Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation											
by RP-UPLC-UV (SOP-0467) % PolyA tailed RNA (% Tailles RNA) by RP-HPLC (SOP-0291) Residual DNA template by qPCR (SOP-0491) pH (SOP-0288) Bacterial endotoxin USP <85.7 h. Eur. 2.6.14 (SOP-0352) Bioburden USP <61.7 h. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation LOO is to the state of the sta											
(SOP-0467) % PolyA nailed 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 <65 - Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation LOGG	% 5' Capped										
% PolyA tailed RNA % Tailless RNA) ys RP-HPLC SOP-0291 Residual DNA template ys qPCR SOP-0491) HI SOP-0288 Bacterial endotoxin USP <85×, Ph. Eur. 2.6.14 SOP-0352) Bioburden USP (SOP-0480) QQ = Limit of Quantitation LOOi and the state of t	(SOP-0467)										
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-0480) Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation	% PolyA tailed RNA										
(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) OQ = Limit of Quantitation	(% Tailless RNA)										
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) OQ = Limit of Quantitation OQ = Limit of Quantitation	(SOP-0291)										
SOP-0491 pH (SOP-0288)	Residual DNA template										
pH (SOP-0288) Bacterial endotoxin USP <85>, Ph. Eur. 2.6.14 (SOP-0352) Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation	by qPCR										
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											
USP <85>, Ph. Eur. 2.6.14 (SOP-0352) Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation	(SOP-0288)										
(SOP-0352) Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation											
Bioburden USP <61>, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation											
USP <61>, Ph. Eur. 2.6.12 (SOP-0480) OQ = Limit of Quantitation											
LOQ = Limit of Quantitation	USP <61>, Ph. Eur. 2.6.12										
LOQ is 100. With the implementation of the parameter change as described in Table 4, Section 3.2.S.3.6 (CX-024414), an expected increase in productivity was achieved and the resultant yield of purified CX-024414 was increased by 100. Bioburden tested using 100. Per Deviation QE-002523.			60								
With the implementation of the parameter change as described in Table 4, Section 3.2.5.2.6 (CX-024414), an expected increase in productivity was achieved and the resultant yield of purified CX-024414 was increased by Bioburden tested using CCI per Deviation QE-002523. Solution 1. Solution 2. Solution 3.2.5.2.6 (CX-024414), an expected increase in productivity was achieved and the resultant yield of purified CX-024414 was increased by CCI per Deviation QE-002523.	1 OO is OO		150								
onfidential This	With the implementation of the paramet	ter change as described in Table 4,	Section 3.2.S.2.6 {CX-0244	14}, an expected increase in	n productivity was achiev	ved and the resultant yield	of purified CX-024414 wa	is increased by			
Ponfidential This document cannot be	e) Bioburden tested using per Dev	riation QE-002523.	00								
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ModernaTX, Inc. 3.2.S.4.4 Batch Analyses {CX-024414}

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

Table 2. Datell Allalyses Da	ita 101 GM1 CA-024414 I	mai scare b (oob 1 v	I) Lots				
CX-024414 GMP Lot Number		4007420001	4007420002	4007420003	4007420010 Lonza Lot 943122	4007420004 31Oct2020 ModernaTX, Inc. Norwood, MA	
Date of Manufacture Manufacturing Location		20Sep2020	03Oct2020	19Oct2020	27Oct2020		
		ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	ModernaTX, Inc. Norwood, MA	Lonza Biologics, Inc. (Portsmouth, NH)		
Purpose		60 L IVT GMP	60 L IVT GMP	60 L IVT PPQ	60 L IVT GMP	60 L IVT PPQ	
IVT Scale		60 T.	60 L	60 T.	60 L	60 1.	
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			
A	Clear, colorless solution	Conforms	Conforms	Conforms	Conforms	Conforms	
Appearance	Essentially free of	Free of visible	Free of visible	Free of visible	Free of visible	Free of visible	
(SOP-0278)	visible particulates	particulates	particulates	particulates	particulates	particulates	
Identity by Reverse Transcription/Sanger Sequencing (SOP-0492)	Sequence matches 100% description of coding region	Conforms	Conforms	Conforms	Conforms	Conforms	
Total RNA content	CCI						
by UV							
(SOP-0249)							
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

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