TABLE OF CONTENT

LIST OF TABLES

DRUG SUBSTANCE CX-024414

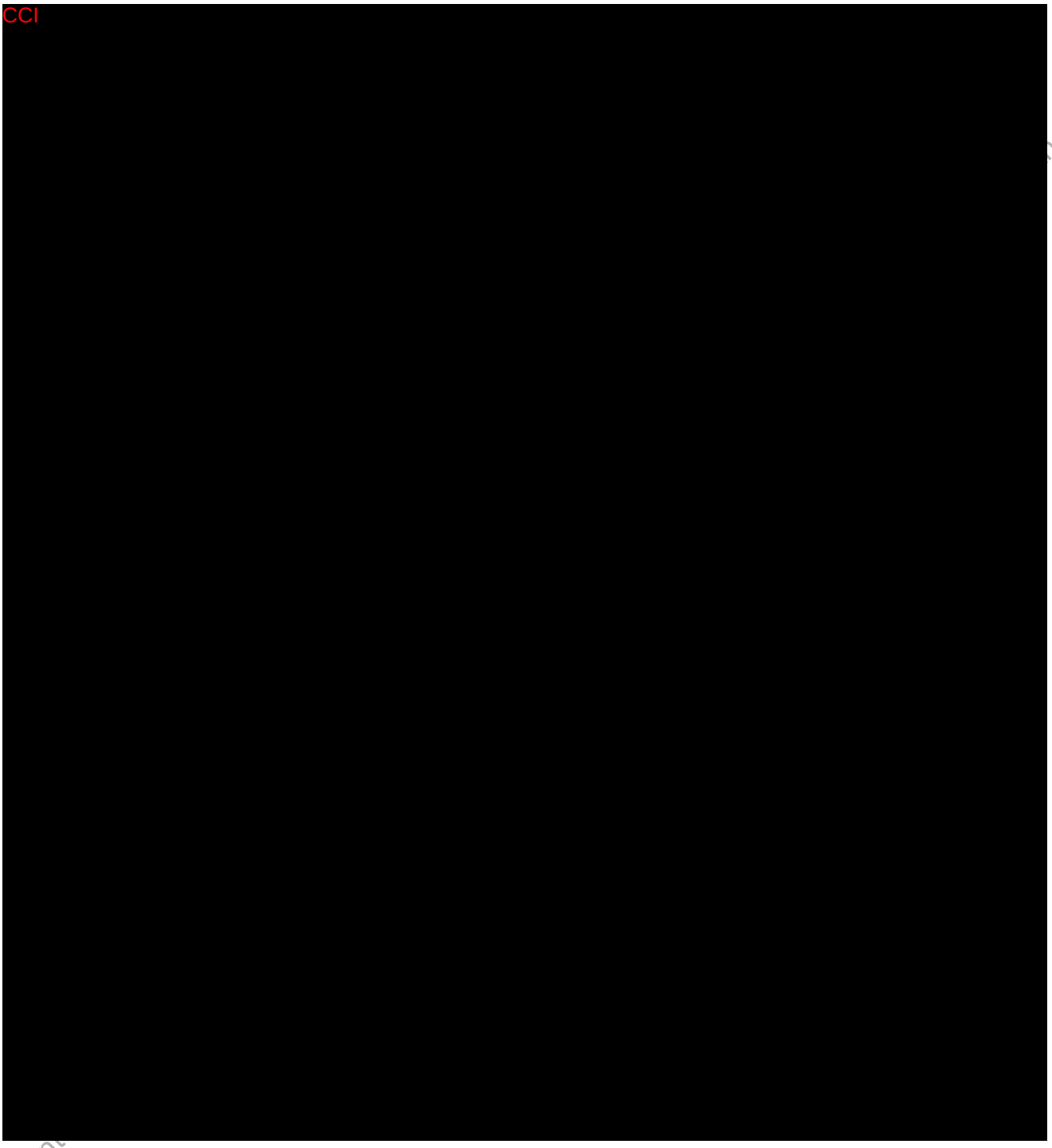
SPECIFICATION CX-024414

Testing of CX-024414 is performed in accordance with the specification listed in Table 1.

Table 1: Specification for CX-024414

Test	Analytical Method (SOP Reference)	Acceptance Criteria
Appearance	Visual Ph. Eur. 2.2.1, 2.2.2 (SOP-0278 ModernaTX, Inc.) (CHVI-101557 Lonza AG)	Clear, colorless solution, essentially free of visible particulates
Identity	Reverse Transcription/Sanger Sequencing (SOP-1019 ModernaTX, Inc.)	Sequence matches 100% description of coding region
Total RNA content	UV (SOP-0995 ModernaTX, Inc.) (GROUP-107939 Lonza AG)	CCI [redacted]
Purity	RP-HPLC (SOP-0996 ModernaTX, Inc.) (GROUP-107927 Lonza AG)	[redacted]
Product-related impurities	RP-HPLC (SOP-0996 ModernaTX, Inc.) (GROUP-107927 Lonza AG)	[redacted]
% 5' Capped	RP-UPLC-UV (SOP-0997 ModernaTX, Inc.) (GROUP-107938 Lonza AG)	[redacted]
% PolyA tailed RNA (% Tailless RNA)	RP-HPLC (SOP-0994 ModernaTX, Inc.) (GROUP-107934 Lonza AG)	[redacted]
pH	USP <791>, Ph. Eur. 2.2.3 (SOP-0288 ModernaTX, Inc.) (CHVI-82391 Lonza AG)	[redacted]
Bacterial endotoxin	USP <85>, EP 2.6.14 (CHVI-6303 Lonza AG) (SOP-0352 Moderna TX, Inc.) (USPO-236 Lonza Biologics, Inc.)	[redacted]
Bioburden	USP <61>, EP 2.6.12 (CHVI-8889 Lonza AG) (SOP-0480 Moderna TX, Inc.) (USPO-3451 Lonza Biologics, Inc.)	[redacted]

CCI



DRUG SUBSTANCE mRNA-1273 Lipid Nanoparticle

SPECIFICATION – mRNA-1273 Lipid Nanoparticle

The specification for mRNA-1273 Lipid Nanoparticle (LNP) is described in Table 3.

Table 3: mRNA-1273 LNP Specification

Test	Analytical Method	Acceptance Criteria
Appearance	Visual Ph. Eur. 2.2.1, 2.2.2 (SOP-0278 ModernaTX, Inc.) (CHVI-101557 Lonza AG) (SOP-0278 Eurofins BioPharma)	White to off-white dispersion. May contain visible, white or translucent product-related particulates.
Identity	Reverse Transcription/Sanger Sequencing (SOP-1032 ModernaTX, Inc.) (SOP-1032 Eurofins BioPharma)	Sequence matches description
Total RNA content	Anion Exchange HPLC (SOP-0999 ModernaTX, Inc.) (GROUP-107933 Lonza AG) (SOP-0999 Eurofins BioPharma)	[redacted]
Purity	RP- HPLC (SOP-0996 ModernaTX, Inc.) (GROUP-107927 Lonza AG) (SOP-0996 Eurofins BioPharma)	
Product-related impurities		
% RNA encapsulation	Fluorescence [redacted] (SOP-1000 ModernaTX, Inc.) (GROUP-108245 Lonza AG) (SOP-1000 Eurofins BioPharma)	
Mean particle size	Dynamic Light Scattering (SOP-0998 ModernaTX, Inc.) (GROUP-109237 Lonza AG) (SOP-0998 Eurofins BioPharma)	
Polydispersity		
Lipid identification		
SM-102	UPLC-CAD (SOP-1001 ModernaTX, Inc.) (GROUP-107937 Lonza AG) (SOP-1001 Eurofins BioPharma)	Matches RT of Standard
Cholesterol		Matches RT of Standard
DSPC		Matches RT of Standard
PEG2000-DMG		Matches RT of Standard
Lipid content		
SM-102	UPLC-CAD (SOP-1001 ModernaTX, Inc.) (GROUP-107937 Lonza AG) (SOP-1001 Eurofins BioPharma)	[redacted]
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid impurities	UPLC-CAD (SOP-1001 ModernaTX, Inc.) (GROUP-107937 Lonza AG) (SOP-1001 Eurofins BioPharma)	Individual impurities: [redacted] area (Report RRT) Total impurities: [redacted] area
pH	USP <791>, Ph. Eur. 2.2.3 (SOP-0288 ModernaTX, Inc.) (CHVI-82391 Lonza AG) (SOP-0288 Eurofins BioPharma)	[redacted]
Osmolality	USP <785>, Ph. Eur. 2.2.35 (SOP-0279 ModernaTX, Inc.) (CHVI-50752 Lonza AG) (SOP-0279 Eurofins BioPharma)	
Bacterial endotoxin	USP <85>, EP 2.6.14 (M-CTS-CS-0929 Associates of Cape Cod) (CHVI-6303 Lonza AG)	
Bioburden	USP <61>, EP 2.6.12 (SOP-0480 ModernaTX, Inc.) (CHVI-8889 Lonza AG)	

Abbreviations: RT= retention time; RRT= relative retention time

DRUG PRODUCT

SPECIFICATIONS

The release specification for mRNA-1273 Drug Product is provided in Table 4.

Table 4: mRNA-1273 Drug Product Release Specification

Test	Method	Acceptance Criteria
Appearance	Visual Ph. Eur. 2.2.1, 2.2.2 (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0278 or Recipharm SUC0190)	White to off-white dispersion. May contain visible, white or translucent product-related particulates.
RNA content	Anion Exchange (AEX) HPLC (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0999 or Recipharm SUC0190, TCC0069)	CCI
Identity	Reverse Transcription/Sanger Sequencing (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-1032)	Sequence matches description
Purity	RP-HPLC (Rovi FA-PT-mRNA-1273 or ModernaTX, Inc. SOP-0996 or Eurofins BioPharma SOP-0996)	CCI
Product-related impurities		
% RNA encapsulation	CCI (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-1000)	
In Vitro Translation	In Vitro Translation/Methionine Labelling (Rovi FA-PT-mRNA-1273 or ModernaTX, Inc. SOP-0937 or Eurofins BioPharma SOP-0937)	
Lipid identification		
SM-102	UPLC-CAD (Rovi FA-PT-mRNA-1273 or ModernaTX, Inc. SOP-1001 or Eurofins BioPharma SOP-1001)	Matches retention time of reference
Cholesterol		Matches retention time of reference
DSPC		Matches retention time of reference
PEG2000-DMG		Matches retention time of reference
Lipid content		
SM-102	UPLC-CAD (Rovi FA-PT-mRNA-1273 or ModernaTX, Inc. SOP-1001 or Eurofins BioPharma SOP-1001)	CCI
Cholesterol		
DSPC		
PEG2000-DMG		
Lipid impurities	UPLC-CAD (Rovi FA-PT-mRNA-1273 or ModernaTX, Inc. SOP-1001 or Eurofins BioPharma SOP-1001)	Individual impurities: CCI area (report RRTs) Total impurities: CCI area
Particle size	Dynamic Light Scattering (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0998)	CCI
Polydispersity		
pH	USP <791>, Ph. Eur. 2.2.3 (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0288 or Recipharm SUC0190)	
Osmolality	USP <785> Freezing Point Depression Ph. Eur. 2.2.35 (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0279 or Recipharm SUC0190)	
Particulate matter		
≥ 25 µm	USP <788>, Ph. Eur. 2.9.19 (Method 2) (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0509 or IFTS PO135)	C per container
≥ 10 µm		CC per container
Container content	USP <697>, Ph. Eur 2.9.17 (Rovi FA-PT-mRNA-1273 or Eurofins BioPharma SOP-0950 or Recipharm SUC0190)	CCI
Bacterial endotoxin	USP <85>, EP 2.6.14	
Sterility	USP <71>, EP 2.6.1	No growth

RRT = relative retention time

The release specifications in Table 4 apply for the stability specification excluding the following stability specifications provided in Table 5.

Table 5: mRNA-1273 Drug Product Stability Specification

Test	Method	Acceptance Criteria
Purity Product-related impurities	RP-HPLC (Rovi FA-PT-mRNA-1273 or ModernaTX, Inc. SOP-0996 or Eurofins BioPharma SOP-0996)	CCI [redacted]
Container Closure Integrity Testing [(a)]	Helium Leak Detection West Pharma (SOP 803-TM)	Passes

(a) Test performed in lieu of Sterility testing in stability