3.2.P.1 DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

mRNA-1273 Drug Product is an mRNA-lipid complex [lipid nanoparticle (LNP)] dispersion that contains an mRNA (CX-024414) that encodes for the pre-fusion stabilized Spike glycoprotein of 2019-novel Coronavirus (SARS-CoV-2) and four lipids which act as protectants and carriers of the mRNA. The four lipids are: SM-102 (a custom-manufactured, ionizable lipid); PEG2000-DMG; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) and cholesterol.

The mRNA-1273 Drug Product is supplied as a multiple-dose liquid ready-to-use solution at 0.20 mg/mL for intramuscular administration in a 10R multiple-dose vial with a rubber serum stopper and an aluminum seal with flip-off plastic cap. Each vial contains 1.26 mg of CX-024414 mRNA and [redacted] as a white to off-white dispersion in preservative-free solution comprising 20 mM tromethamine (Tris), [redacted] acetate, 87 g/L sucrose buffer at pH 7.5. There are 10 doses per vial. The mRNA-1273 Drug Product presentation information is provided in Table 1. The mRNA-1273 Drug Product composition is provided in Table 2.

Table 1: mRNA-1273 Drug Product Presentation

mRNA Strength	0.20 mg/mL
Vial	10R Type 1 glass (Ompi) 10R Valor® Type 1 equivalent glass (Corning)
Stopper	[redacted]
Seal	Aluminum Seal with Flip-off Plastic cap Color: Red Matte
Target Fill Volume/Vial	6.3 mL
Nominal (= Label) Fill Volume	5.0 mL
Nominal Doses/Vial	10 (target)
Site of Manufacture	Rovi Pharma Industrial Services, S.A. Paseo de Europa, 50 (Carretera, Madrid, 14Y) 28709. San Sebastian de los Reyes Madrid, Spain
Long-term Storage Condition	-20°C ± 5°C

*"F" designates the presence of a FluroTec® coating

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Table 2: mRNA-1273 Drug Product Composition

Component		Grade	Function	Unit Formula (mg/mL)	Unit Formula (mg/vial) (6.3 mL fill)
CX-024414		Custom	mRNA that encodes for the pre-fusion stabilized Spike glycoprotein of 2019-novel Coronavirus (SARS-CoV-2)	0.20	1.26
[redacted]	SM-102	Custom	Lipid Nanoparticles	[redacted]	[redacted]
	Cholesterol	USP, Ph. Eur.			
	DSPC	Non-compendial			
	PEG2000-DMG	Non-compendial			
Tromethamine (Tris)		Ph. Eur., USP	Buffer components for Tris buffer [a]		
Tromethamine-HCl (Tris-HCl)		Non-compendial			
Acetic acid (Glacial)		USP/NF, Ph. Eur.	Buffer components for Sodium acetate buffer in LNP		
Sodium acetate		Compendial or Non-compendial [b]			
Sucrose		USP/NF, Ph. Eur.	Cryoprotectant	87	548
Water for Injection		USP, Ph. Eur.	Medium	q.s. 1.0 mL	q.s. 6.3 mL

Abbreviations: DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; LNP = lipid nanoparticle; N/A = not applicable; q.s. = quantum sufficit

a) Target pH 7.5

b) Sodium acetate content is carryover from drug substance Sodium Acetate buffer. One option for the manufacture of Sodium acetate buffer is with glacial acetic acid and 10 N sodium hydroxide (30% w/w). Sodium acetate for this option is defined as non-compendial, as it is manufactured with glacial acetic acid (USP, Ph. Eur.) and 10 N sodium hydroxide (30% w/w), which is non-compendial. The second option for the manufacture of Sodium acetate buffer is with glacial acetic acid and sodium acetate trihydrate. Sodium acetate for this option is defined as compendial, as both glacial acetic acid (USP, Ph. Eur.) and sodium acetate trihydrate (USP, Ph. Eur.) are compendial reagents.

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