

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. (b) (4)

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 SiOPlas™ (SIO2 Materials Science)
Stopper	20 mm West 4432-50 GY S10-F451* B240 Westar
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	Catalent Indiana, LLC 1300 South Patterson Drive Bloomington, Indiana 47403 USA
Long-term Storage Condition	-20°C ± 5°C (a)

*"F" designates the presence of a FluroTec coating

a) Vials are (b) (4) to be transferred to -20°C for long-term storage.

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(b) (4)

