

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

mRNA-1273 Drug Product (DP) [Generic Name (INN): Elasomeron; Established Names: Spikevax™, Moderna COVID-19 Vaccine, COVID-19 Vaccine Moderna) 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 that act as protectants and carriers of the mRNA. The four lipids are: SM-102 (a custom-manufactured, ionizable lipid); PEG2000-DMG; DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine); and cholesterol.

The mRNA-1273 DP is supplied as a multiple-dose liquid, ready-to-use solution at 0.20 mg/mL for intramuscular administration in 10-mL (10R) vials, are closed with a rubber stopper and aluminum crimp flip-off seal, detailed in [Table 1](#) and discussed in [Sections 3.2.P.2.4](#) and [3.2.P.7](#).

mRNA-1273 DP is provided in two vial presentations:

Maximum 11-dose (0.5 mL per dose) vial: Each vial contains (b) (4) mg of CX-024414 mRNA and (b) (4) mg of SM-102 LNP as a white to off-white dispersion in a preservative-free buffer containing 20 mM Tromethamine (Tris), (b) (4) acetate, 87 g/L sucrose at pH 7.5. The target fill volume is 6.3 mL, which allows removal of a maximum of 11 doses (0.5 mL per dose) per vial. The label fill volume is 5.5 mL.

Maximum 15-dose (0.5 mL per dose) vial: Each vial contains (b) (4) mg of CX-024414 mRNA and (b) (4) mg of SM-102 LNP as a white to off-white dispersion in a preservative-free buffer containing 20 mM Tromethamine (Tris), (b) (4) acetate, 87 g/L sucrose at pH 7.5. The target fill volume is 8.0 mL, which allows removal of a maximum of 15 doses (0.5 mL per dose) per vial. The label fill volume is 7.5 mL.

Details of the mRNA-1273 DP presentations are provided in [Table 1](#). The mRNA-1273 DP 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) RTU or Bulk 10 mL SiOPlas™ (SiO2 Materials Science) RTU 10R Valor® (Corning) Bulk 10R Velocity® (Corning) Bulk
Stopper	20 mm West 4432-50 GY S10-F451 ^(a) B2 Westar (RU and RS) 20 mm West 4432-50 GY S10-F451 ^(a) B2 NovaPure Westar (RU and RS)
Seal	Aluminum Seal with Flip-off Color: Red Matte
Target fill volume/vial	6.3 mL 8.0 mL
Nominal doses/vial	Maximum 11 doses of 0.5 mL each (Label fill volume: 5.5 mL) Maximum 15 doses of 0.5 mL each (Label fill volume: 7.5 mL)
Sites of manufacture	Catalent Indiana, LLC 1300 South Patterson Drive Bloomington, Indiana 47403 USA Baxter Pharmaceutical Solutions, LLC 927 S. Curry Pike Bloomington, Indiana 47403 USA
Long-term storage condition	-50°C to -15°C

Abbreviations: RS, RTS = ready-to-sterilize; RU, RTU = ready-to-use

^a “F” designates the presence of a FluroTec® coating

(b) (4)

