

3.2.P.1 Description and Composition of the Drug Product

mRNA-1273 LS Injection (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 protein 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.

mRNA-1273 LS Injection has a total lipid content of (b) (4) mg/mL and contains 20 mM trometamol (Tris), 87 mg/mL sucrose and (b) (4) sodium acetate at a dosage strength of 0.20 mg/mL mRNA, pH 7.5. mRNA-1273 LS Injection is presented in 10R USP Type I borosilicate glass vials with (b) (4)

(b) (4) mRNA-1273 LS Injection is stored (long-term) between -60°C to -90°C. Prior to use in the clinical studies, mRNA-1273 LS Injection will be thawed and stored (short-term) at 2°C to 8°C. One vial of mRNA-1273 LS Injection contains 6 doses for intramuscular injection (0.5 mL each).

The quantitative composition of the components in mRNA-1273 LS Injection is presented in [Table 1](#).

(b) (4)

