

3.2.P.2.1 Components of the Drug Product

The mRNA-1273 Injection manufacturing process consists of the dilution of the mRNA-1273 LS Lipid Nanoparticle (LNP) with a formulation buffer containing 20 mM Tris and 87 mg/mL sucrose, pH 7.5. The name, function and unit quantity of the components of mRNA-1273 Drug Product are shown in Table 1.

Table 1: Components of mRNA-1273 Injection

Component	Function	Quantity (mg/mL)
CX-024414	mRNA that encodes for the pre-fusion stabilized Spike protein of 2019-novel Coronavirus (SARS-CoV-2)	0.20
SM-102	Lipid components in the SM-102 LNP	
Cholesterol (plant-based)		
1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)		
PEG2000-DMG		
Trometamol	Buffer component (Tris buffer)	0.61
Trometamol-HCl		2.35
Acetic Acid	Components from Sodium Acetate in process	0.085
Sodium Acetate		
Sucrose	Cryoprotection	87
Water for injection	Medium	q.s. to 1 mL

a) PEG2000-DMG quantity is from SM-102 LNP content and PEG2000-DMG addition step.

b) Sodium acetate quantity is from buffer(s) manufactured with glacial acetic acid and 10 N sodium hydroxide (30% w/w).