

3.2.P.3.2 Batch Formula

A representative 10 gram batch size and formula for the manufacture of mRNA-1273 Drug Product are provided in Table 1 and Table 2. Manufacture at the fill finish site uses the compounding formula in Table 3. Theoretical number of vials and component amounts per batch are adjusted based on mRNA input.

Table 1: mRNA-1273 Drug Product Batch Size

Product (strength)	Batch Size	Theoretical Number of Vials
0.20 mg/mL mRNA	10 grams mRNA	7,500 vials

Table 2: mRNA-1273 Drug Product Batch Formula

Component	Amount per Batch (grams unless noted) ^(a)
CX-024414 (mRNA)	
Sucrose, USP/NF, Ph. Eur.	
Glacial Acetic Acid, USP, Ph. Eur.	
Sodium Acetate	
Tris (Base), USP, Ph. Eur.	
Tris HCl	
Water for Injection	

a) Amounts per batch are based on a target mRNA input of 10.0 grams and will adjust based on mRNA input.

b) Sodium acetate unit amount is from buffer(s) manufactured with glacial acetic acid and sodium hydroxide

Table 3: mRNA-1273 Drug Product Batch Manufacturing Formula

Component	Amount per Batch (grams unless noted)
mRNA-1273 LNP	10.0 mRNA
Dilution Buffer ^(a)	Calculated ^(b)

a) Dilution Buffer composition in WF1 (0.398 g/L Tris, 2.63 g/L Tris HCl, 87 g/L Sucrose, pH 7.5), density =

b) Target weight of dispensed Dilution Buffer = Density of Dilution Buffer * [(Volume of pooled and clarified mRNA-1273 LNP x mRNA concentration of pooled and clarified mRNA-1273 LNP/DP Final Dilution target concentration) – Volume of pooled and clarified mRNA-1273 LNP]