

3.2.P.3.2. BATCH FORMULA – PRE-FILLED SYRINGE

The target batch size for BNT162b2 PFS drug product may vary [REDACTED] 4.2 1st. ind. [REDACTED]
[REDACTED], corresponding to a bulk drug product solution [REDACTED] 4.2 1st. ind. [REDACTED]
A bulk drug product solution [REDACTED] 4.2 1st. ind. [REDACTED] can be split into [REDACTED]
sublots.

The syringe filling batch size of bulk drug product at 0.1 mg/mL RNA is maximum [REDACTED] 4.2 1st. ind. [REDACTED]
[REDACTED]

The syringe filling batch size of bulk drug product at 0.1 mg/mL RNA is maximum [REDACTED] 4.2 1st. ind. [REDACTED]
[REDACTED]

Table 3.2.P.3.2-1 presents the unit formula for one liter of formulated BNT162b2
Monovalent bulk drug product and the batch formulas [REDACTED] 4.2 1st. ind. [REDACTED]

Table 3.2.P.3.2-1. Batch Formula for BNT162b2 Monovalent Bulk Drug Product^a

Name of Ingredients	Reference to Standard	Unit Formula per 1 L (g)	Quantity per 70 g RNA Batch (g)	Quantity per 220 g RNA Batch (g)
BNT162b2 drug substance	In-house specification	4.2 1st. ind.		
ALC-0315	In-house specification			
ALC-0159	In-house specification			
DSPC	In-house specification			
Cholesterol	Ph. Eur.			
Sucrose	USP-NF, Ph. Eur			
Tromethamine	Ph. Eur, USP-NF, JP			
Tris Hydrochloride	In-house specification			
Water for Injection	USP-NF, Ph. Eur			
Processing Aids/Residues ^c				
Ethanol	Ph. Eur.	N/A		
Citric acid monohydrate	Ph. Eur.			
Sodium citrate	Ph. Eur.			
Sodium hydroxide	Ph. Eur.			
HEPES	In-house specification			
EDTA	Ph. Eur., USP-NF			

a. Provisions are made to manufacture batches of Tris/Sucrose drug product **4.2 1st. ind.**

b. A theoretical bulk drug product batch volume **4.2 1st. ind.** is included in the batch formula table corresponding to the maximum validated ingoing RNA quantity for LNP production. In practice, the maximum bulk drug product batch volume for sterile filtration and filling is limited **4.2 1st. ind.** as this is currently the maximum validated volume for a single lot.

c. The processing aids and drug substance formulation buffer components are residues that are essentially removed through the manufacturing process and are not considered ingredients (excipients).

Abbreviations: ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; q.s. = quantum satis (as much as may suffice); HEPES = 4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid; EDTA = edetate disodium dihydrate; N/A = not applicable