

### **3.2.P.1. DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT – [OMICRON (KP.2) VARIANT] - PRE-FILLED SYRINGE (REFRIGERATED, GLASS)**

The BNT162b2 drug product in a pre-filled syringe (PFS) is supplied as a preservative-free, sterile dispersion of RNA-containing lipid nanoparticles (LNPs) in aqueous cryoprotectant buffer for intramuscular administration. The BNT162b2 PFS is formulated at 0.1 mg/mL RNA in 10 mM Tris buffer, 300 mM sucrose, pH 7.4.

The single-dose glass pre-filled syringe presentation is filled at 0.418 mL fill volume and is administered without dilution, providing a single 30 µg RNA dose in 0.3 mL injection volume.

The drug product is supplied in a 1 mL Type I borosilicate glass syringe closed with a bromobutyl elastomeric tip cap and plunger stopper and a non-product contacting rigid polypropylene cap.

The composition of the drug product, including quality standard, function, concentration, total amount per syringe and amount per dose is provided in [Table 3.2.P.1-1](#).

**Table 3.2.P.1-1. Composition of BNT162b2 PFS Drug Product, 30 µg RNA dose in 0.3 mL Injection Volume, Single dose Pre-filled Syringe**

Name of Ingredients	Reference to Standard	Function	Concentration (mg/mL)	Amount per 0.418 mL syringe <sup>a</sup>	Amount per Dose
BNT162b2 Omicron (KP.2) Variant drug substance	In-house specification	Active ingredient	0.1	42 µg	30 µg
ALC-0315	In-house specification	Functional lipid	1.43	0.598 mg	0.43 mg
ALC-0159	In-house specification	Functional lipid	0.18	0.075 mg	0.05 mg
DSPC	In-house specification	Structural lipid	0.31	0.130 mg	0.09 mg
Cholesterol	Ph. Eur.	Structural lipid	0.62	0.259 mg	0.19 mg
Sucrose	USP-NF, Ph. Eur.	Cryoprotectant	103	43.1 mg	31 mg
Tromethamine (Tris base) <sup>b</sup>	USP-NF, Ph. Eur.	Buffer component	0.20	0.084 mg	0.06 mg
Tris (hydroxymethyl) aminomethane hydrochloride (Tris HCl) <sup>c</sup>	In-house specification	Buffer component	1.32	0.552 mg	0.4 mg
Water for Injection	USP-NF, Ph. Eur.	Solvent/vehicle	q.s.	q.s.	q.s.
<b>Processing Aids/Residues<sup>d</sup></b>					
Ethanol	Ph. Eur.	Processing aid	N/A		
Citric acid monohydrate	Ph. Eur.	Processing aid			
Sodium citrate	Ph. Eur.	Processing aid			
Sodium hydroxide	Ph. Eur.	Processing aid			
HEPES	In-house specification	Drug substance buffer component			
EDTA	Ph. Eur., USP-NF	Drug substance buffer component			

a. Values are rounded to maintain the same level of precision as the label claim, with trailing decimals not shown, where applicable.

b. Also known as Trometamol

c. Also known as Tromethamine HCl and Trometamol HCl

d. 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).

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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

### **Overfill**

The target fill volume for the PFS drug product is 0.418 mL which includes an overfill of 0.118 mL to ensure a nominal volume of 0.3 mL is delivered when an appropriate needle for intramuscular injection is used with this syringe.

### **Overage**

There is no manufacturing overage.