

3.2.P.3.2. BATCH FORMULA

The target drug product batch size (b) (4)
Table 3.2.P.3.2-1 presents the unit formula for one liter of formulated bulk drug product solution, as well as batch formulas for representative batch sizes of (b) (4)

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

Name of Ingredients	Reference to Standard	Unit Formula per 1 L (g)
BNT162b2 drug substance	In-house specification	0.5
ALC-0315	In-house specification	7.17
ALC-0159	In-house specification	0.89
DSPC	In-house specification	1.56
Cholesterol	Ph. Eur. and/or USP-NF	3.1
Sucrose	Ph. Eur., USP-NF	(b) (4)
Sodium chloride	Ph. Eur., USP-NF	6
Potassium chloride	Ph. Eur. and/or USP-NF	0.15
Dibasic sodium phosphate, dihydrate ^a	Ph. Eur., USP-NF	1.08
Monobasic potassium phosphate ^b	Ph. Eur. and/or USP-NF	0.15
Water for Injection	Ph. Eur., USP-NF	q.s. (b) (4)

a. Dibasic sodium phosphate, dihydrate is named as disodium phosphate dihydrate in the Ph. Eur.

b. Monobasic potassium phosphate is named as potassium dihydrogen phosphate in the Ph. Eur.

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, meaning as much as is sufficient

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