3.2.P.3.4. PROCESS STEPS HOLD TIMES – FILL AND FINISH – PRE-FILLED SYRINGE [PUURS]

3.2.P.3.4.1. Process Hold Times

During process development, studies were performed to determine acceptable hold times for drug substance and bulk drug product during the drug product manufacturing process. Hold times were confirmed during process validation studies.

Table 3.2.P.3.4-1 shows the hold times for the BNT162b2 drug product in-process materials during sterile filtration, fill and finish, inspection and secondary packaging for glass syringes. All hold times following sterile filtration were verified and consistent with the validated media fill times, ensuring acceptable microbial control during the drug product manufacturing process. The sterile filtration processing steps are within the maximum times determined by the bacterial retention filter validation.

Table 3.2.P.3.4-1. Fill and Finish Process Hold Times – PFS (Refrigerated, Glass)

Material or In-Process Hold Description	Process Steps	Category	Target Hold Time
4.2 1st ind			

3.2.P.3.4.2. Process Parameters for Product Handling, Redistribution and Storage During Transport of BNT162b2 PFS (Refrigerated, Glass)

Process Parameters for Product Handling, Redistribution and Storage During Transport of BNT162b2 PFS (Refrigerated, Glass)

Process parameters for product handling, redistribution and storage during transport have been established for BNT162b2 refrigerated drug product in glass PFS as detailed in Table 3.2.P.3.4-2.

Table 3.2.P.3.4-2. Process Parameter for Product Handling, Redistribution and Storage During Transport

Process Parameter	Acceptable Range
4.2 1st ind	