3.2.P.5.3. OVERVIEW

Validation of analytical procedures was performed to ensure the composition, strength, identity, potency, purity, and safety of BNT162b2 drug product. All non-compendial and compendial analytical procedures were confirmed suitable for their intended use.

Analytical procedures were validated against the parameters presented in ICH Q2(R1), Validation of Analytical Procedures: Text and Methodology, for the respective methodology categories. Quantitative analytical procedures were validated for precision, accuracy, specificity, linearity, range, and robustness. (b) (4)

(b) (4)

Summaries of the non-compendial and microbiological compendial validations/verifications performed for BNT162b2 drug product release and stability analytical procedures are provided in this section, except (b) (4) which are provided in Section 3.2.S.4.3 Validation of Analytical Procedures. As requested by FDA, the analytical method validation and transfer reports are presented in Section 3.2.R Standard Operating Procedures, Method Validation and Transfer Reports.