3.2.S.4.3. VALIDATION OF ANALYTICAL PROCEDURES – OVERVIEW

This section contains information specific for presentation Tris/sucrose Comirnaty [Original and Omicron (B.1.1.529)], which is discontinued. For information purposes, non-compendial analytical method information supportive of the stability data is maintained, along with the corresponding analytical validation information.

3.2.S.4.3.1. Analytical Procedures Used for Release and Stability Testing

Validation or verification of analytical procedures for the BNT162b2 original drug substance (DS) was performed to ensure composition, strength, identity, purity, and safety. Non-compendial analytical procedures were confirmed suitable for their intended use by assessing all relevant validation elements described in ICH Q2 (R1), Validation of Analytical Procedures: Text and Methodology. Compendial analytical procedures were verified or validated according to the appropriate USP, Ph. Eur., and JP chapters.

The Omicron (B.1.1.529) variant differs from the original vaccine in the sequence and length of the mRNA. The DS concentration, formulation process, quality attributes, and process control remain unchanged in the Omicron (B.1.1.529) variant drug substance. Identical test methods used for the original drug substance are used for the Omicron (B.1.1.529) variant drug substance apart from the method for identity by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) which requires Omicron (B.1.1.529) variant specific reagents. The validation of RT-PCR is presented in Section 3.2.S.4.3 Validation of Analytical Procedures – RT-PCR [Omicron B.1.1.529 Variant]. A calculation is incorporated into the Quantitative Polymerase Chain Reaction (qPCR) method to account for variant base pair sizes but does not impact the validated state of the assay.

The remainder of the DS analytical procedures are not impacted by the change to the mRNA sequence and do not require additional validation for the Omicron (B.1.1.529) variant. Therefore, laboratories and test methods previously verified/validated for the testing of BNT162b2 original drug substance are considered suitable for testing of Omicron (B.1.1.529) variant.