

2.3.S.4. CONTROL OF DRUG SUBSTANCE,OMICRON (BA.4/BA.5) VARIANT

This section contains information specific for presentation Comirnaty [Original and Omicron (BA.4/BA.5)], which is discontinued. For information purposes, data/information supportive of the platform development approach for other presentations is maintained.

2.3.S.4.4. Batch Analyses

Omicron (BA.4/BA.5) variant drug substance batches used for clinical trials, small scale development, large scale confirmatory, and stability are summarized in [Section 3.2.S.4.4 Batch Analyses \[Omicron \(BA.4/BA.5\) Variant\]](#).

A full drug substance genealogy can be found in [Section 3.2.S.2.6 Manufacturing Process Development - Developmental History and Comparability Assessment \[Omicron \(BA.4/BA.5\) Variant\]](#).

2.3.S.4.5. Justification of Specification

The specification for Omicron (BA.4/BA.5) variant drug substance is based on an understanding of the control strategy and CQAs for the BNT162b2 original drug substance. For subsequent constructs (i.e variant DS) introduced after the Omicron (BA.1) variant, the historical data and relevant assessments from the Original drug substance are confirmed applicable, applied and unchanged, with the exception of identity. The attributes tested and associated acceptance criteria ensure the consistency of drug substance and linkage to clinical experience. This specification was established to ensure the quality, purity, potency/biological activity and safety of the commercial drug substance at release and during storage Specification-Setting Strategy.

Because there are no significant trends that would impact the shelf life of the drug substance

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the acceptance criteria used for stability over shelf life are the same as the acceptance criteria used for batch release. In summary, the acceptance criteria in the drug substance specification reflect the current understanding of criticality of quality attributes, their impact on product performance, their stability, and the quality of the product used in clinical trials.