3.2.S.4.3. QUANTITATIVE POLYMERASE CHAIN REACTION (qPCR)

3.2.S.4.3.1. Overview

The qPCR analytical procedure for the determination of residual DNA template content has been validated for BNT162b2 drug substance (DS) in conformance with ICH Q2(R1) guidelines.

This section references the validation and transfer report numbers that detail the testing, experimental design, method evaluation, acceptance criteria and results for the validation and transfer of the analytical procedure. The type of validation, involved sites, and references to the validation and transfer reports are provided in Table 3.2.S.4.3-1.

Table 3.2.S.4.3-1. BNT162b2 Drug Substance method Validation and Transfer Reports for qPCR

Validation or Transfer	Site(s)	Report
Co-validation	4.2 1st ind [redacted]	VAL100146017 Report for the Validation of Test Method TM100010388 - Quantitation of Residual DNA Template ([redacted]) in PF-07305885 Drug Substance Using qPCR Technology
Validation		MVR-20-0007-qPCR and MVR-21-0006-V01-qPCR
Transfer		RPT-140496: Transfer Report for Drug Substance Quantitative Polymerase-Chain Reaction (qPCR) Assay [redacted]
4.2 1st ind [redacted]		