

3.2.S.4.3. DROPLET DIGITAL POLYMERASE CHAIN REACTION (ddPCR)

3.2.S.4.3.1. Overview

The ddPCR analytical procedure for the quantitation of mRNA poly(A) tail in BNT162b2 drug substance (DS) has been validated 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 ddPCR

Validation or Transfer	Site(s)	Report
Co-Validation	4.2 1st ind	VAL100146747 Report for the Validation of Test Method TM100010379 - Quantitation of Poly A Tail in BNT162b2 mRNA PF-07305885 (Drug Substance) using ddPCR Technology
Validation		VAL-3024-VB-01_en 4.2 1st ind
Transfer		RPT-140497 Transfer report for Transfer of digital droplet Polymerase Chain Reaction (ddPCR) Assay 4.2 1st ind
4.2 1st ind		