

3.2.S.4.3. CAPILLARY GEL ELECTROPHORESIS (CGE)

3.2.S.4.3.1. Overview

The capillary gel electrophoresis analytical procedure for the determination of RNA integrity has been validated for BNT162b2 drug substance (DS) and drug product (DP) 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 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 and Drug Product Method Validation and Transfer Reports

Validation/Verification or Transfer	Site(s)	Report
Validation	4.2 1st ind [REDACTED]	VAL100136603: Report for the Validation of the Method TM100010392: RNA integrity of mRNA drug substance and LNP-mRNA drug product samples by fragment analyzer (CGE)
Method transfer		RPT-124539: Method Transfer Waiver Report for the Determination of RNA Integrity by Fragment Analyzer 4.2 1st ind [REDACTED]
Method Transfer		INX100458163: Analytical Method Transfer Exercise (AMTE) Report for TM100010392 v5.0 Fragment Analyzer to test LNP-mRNA Drug Product 4.2 1st ind [REDACTED]
Validation		MVR-20-0018: Determination of RNA integrity in DS samples (BNT162/CorVac)
		MVR-21-0004: Determination of RNA integrity in DP samples (BNT162/CorVac)
Validation		VAL-3022-VB-01: RNA integrity (CorVac DS/DP)
Validation		V-Q-125-01: RNA Integrity of mRNA-LNP vaccine BNT162b2 by Fragment Analyzer (capillary electrophoresis)
Method Transfer		VAL-M-094_TB01_V01: Capillary Gel Electrophoresis for the Determination of the Purity of RNA
Validation		MVR-580946: Determination of mRNA Integrity through Fragment analysis of BNT162b2 DP Tris/ Sucrose Formulation and BNT162b2 DP PBS/ Sucrose Formulation
Transfer		INX100475657, Analytical Method Transfer Exercise (AMTE) Report for TM100010392 Fragment Analyzer to Test Drug Substance PF-0705885 4.2 1st ind [REDACTED]
4.2 1st ind	[REDACTED]	