

3.2.S.4.3. IMMUNOBLOT

3.2.S.4.3.1. Overview

The immunoblot analytical procedure has been validated as a limit test for semi-quantitation of double stranded RNA (dsRNA) content in 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 Immunoblot

Validation or Transfer	Site(s)	Report
Co-validation	4.2 1st ind	VAL100138332: Report for Validation of Test Method TM100010474 - Immunoblot Assay for Analysis of dsRNA in PF-07305885 Modified RNA Drug Substance
Validation		VAL-3247-VB-01-Immunoblot
Transfer		RPT-134194, Analytical Method Transfer Exercise (ATME) Report for Method Transfer for Determination of dsRNA Concentration by Immunoblot Analysis of BNT162b2 (PF-07305885)
4.2 1st ind		4.2 1st ind