3.2.S.4.3. REVERSED PHASE-HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (RP-HPLC)

3.2.S.4.3.1. Overview

The reverse phase high performance liquid chromatography (RP-HPLC) analytical procedure for the determination of the 5'-cap content 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 5' -Cap Content

Validation or Transfer	Site(s)	Report
Co-validation	4.2 1st ind	VAL100136648, Report for the Validation of TM100010578, mRNA 5'Cap Relative Quantification by 4.2 1st Digestion, 4.2 1st ind i Affinity Purification, and LC-UV Analysis for PF-07305885
Transfer		RPT-131861, Analytical Method Transfer Exercise (AMTE) Report for Method Transfer for modRNA 5'Cap Relative Qualification of BNT162b2 (PF-07305885) 4.2 1st ind

4.2 1st ind