

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

3.2.S.4.3.1. Overview

The ion pair-reversed phase-high performance liquid chromatography (IP-RP-HPLC) analytical procedure for the determination of poly(A) tail length in BNT162b2 drug substance (DS) has been validated in conformance with ICH Q2(R1) guidelines.

This section references the validation and transfer report number 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 reference 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 IP-RP-HPLC

Validation/Verification or Transfer	Site(s)	Report
Co-validation	4.2 1st ind	VAL100144431: Confirmation of the 3' Poly(A) Tail Length of mRNA by RNase T1 and RNase A Digestion and IP-RP-HPLC/UV Analysis for PF-07305885 Drug Substance
Validation		940199: Method Validation Report of the Verification of 3' Poly(A) Tail Length of BNT162b2 by RP-HPLC
Transfer		RPT-131863 Analytical Method Transfer Exercise (AMTE) Report for Method Transfer for Confirmation of the 3' Poly(A) Tail Length of mRNA of BNT162b2 (PF-07305885) 4.2 1st ind
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