

3.2.S.4.3. UV SPECTROSCOPY

3.2.S.4.3.1. Overview

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 UV Spectroscopy

Validation or Transfer	Site(s)	Report
Validation	4.2 1st ind	VAL100131625, Report for the validation of TM100010308 determination of RNA Concentration in RNA Drug Substance by UV Spectroscopy
Transfer	4.2 1st ind	INX100439722: Analytical Method Transfer Exercise (AMTE) Report for TM100010308 4.2 1st ind to Test In-Process and Drug Substance PF-07305885
Validation	4.2 1st ind	MVR-20-0005: Determination of RNA content by UV/VIS (CorVac/BNT162)
Transfer	4.2 1st ind	RL-Report-09484: Method Transfer Report: Transfer of the Method for RNA Content Determination of BNT162 by A260
Transfer	4.2 1st ind	ANMT_AMTR_00545373: Transfer Report – Determination of content by UV/VIS (CorVac/BNT162)
Transfer	4.2 1st ind	RPT-131860, Analytical Method Transfer Exercise (AMTE) Report for Method Transfer for Determination of RNA Concentration by UV Spectroscopy and 4.2 1st ind for Purification of BNT162b2 (PF-07305885) 4.2 1st ind

4.2 1st ind

4.2 1st ind

UV = ultraviolet; 4.2 1st ind