

3.2.S.4.2. OVERVIEW

Analytical procedures for drug substance (DS) release and stability testing are listed in Table 3.2.S.4.2-1. The analytical procedures used for testing the variant DS are identical to those established for testing of previously approved BNT162b2 vaccine DS.

Table 3.2.S.4.2-1. Analytical Procedures for Drug Substance

Analytical Procedure	Quality Attribute
Appearance	Clarity and Coloration
Potentiometry	pH
UV Spectroscopy	Content (RNA Concentration)
ddPCR for Identity or RT-PCR for Identity	Identity of encoded RNA sequence
RP-HPLC	5'-Cap
ddPCR	Poly (A) Tail
IP-RP-HPLC	Poly (A) Tail Length
qPCR	Residual DNA Template
Immunoblot	Residual dsRNA
Capillary Gel Electrophoresis	RNA Integrity
Endotoxin (LAL)	Bacterial Endotoxin
Bioburden	Bioburden

Abbreviations: ddPCR = digital droplet polymerase chain reaction, dsRNA = double stranded RNA, LAL = limulus amoebocyte lysate, qPCR = quantitative polymerase chain reaction, RP-HPLC = reversed phase-high performance liquid chromatography, RT-PCR = reverse transcription-polymerase chain reaction, IP-RP-HPLC = ion pair reversed phase-high performance liquid chromatography