3.2.S.4.1. SPECIFICATION

The specification for BNT162b2 drug substance at release and during stability studies is provided in Table 3.2.S.4.1-1. (b) (4) The acceptance criteria provided are based on the available data.

Table 3.2.S.4.1-1 BNT162b2 Drug Substance Specification

Quality Attribute	Analytical Procedure	Acceptance Criteria
Composition and Strength		(b) (4)
Clarity	Appearance (Clarity) *(Ph. Eur. 2.2.1)*	
Coloration	Appearance (Coloration) *(Ph. Eur. 2.2.2)*	
pH	(b) (4) *(Ph. Eur. 2.2.3, USP <791>)*	
Content (RNA Concentration)	UV Spectroscopy	
Identity		
Identity of Encoded RNA Sequence	RT-PCR[a]	
Purity		
RNA Integrity	Capillary Gel Electrophoresis	
5'- Cap	RP-HPLC	
Poly(A) Tail	ddPCR	
Process Related Impurities		
Residual DNA Template	qPCR[a]	
Product Related Impurities		
dsRNA	Immunoblot[a]	
Safety		
Bacterial Endotoxin	Endotoxin (LAL) *(Ph. Eur 2.6.14, USP <85>, JP 4.01)*	
Bioburden	Bioburden *(Ph. Eur. 2.6.12, USP <61>, JP 4.05)*	

a. Assay not performed on stability.
Abbreviations: NTU = Nephelometric Turbidity Units; B = brown; RT-PCR = reverse transcription polymerase chain reaction; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amebocyte lysate; EU = endotoxin unit; CFU = colony forming unit