

3.2.P.5.1. SPECIFICATION(S)

The specification for BNT162b2 drug product at release and throughout shelf life is provided in [Table 3.2.P.5.1-1](#). For all quality attributes (b) (4)

[REDACTED]

Table 3.2.P.5.1-1. BNT162b2 Drug Product Specification

Quality Attribute	Analytical Procedure ^a	Acceptance Criteria	
Composition and Strength			
Appearance	Appearance (Visual)	White to off-white suspension	
Appearance (Visible Particulates)	Appearance (Particles) (Ph. Eur. 2.9.20, USP <790>, JP 6.06)	May contain white to off-white opaque, amorphous particles	
Subvisible Particles	Subvisible Particulate Matter (USP <787>, light obscuration method)	(b) (4)	
pH	(b) (4) (Ph. Eur. 2.2.3, USP <791>)	6.9 – 7.9	
Osmolality	Osmometry ^{b,c} (USP <785>)	(b) (4)	
LNP Size	Dynamic Light Scattering (DLS)	(b) (4)	
LNP Polydispersity	Dynamic Light Scattering (DLS)		
RNA Encapsulation	Fluorescence assay		
RNA content	Fluorescence assay		
ALC-0315 content	HPLC-CAD		
ALC-0159 content	HPLC-CAD		
DSPC content	HPLC-CAD		
Cholesterol content	HPLC-CAD		
Vial content (volume)	Container content ^c		Not less than (b) (4)
Identity			
Lipid identities	HPLC-CAD ^c	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	
Identity of encoded RNA sequence	RT-PCR ^c	Identity confirmed	
Potency			
In Vitro Expression	Cell-based flow cytometry	(b) (4)	
Purity			
RNA Integrity	Capillary Gel Electrophoresis	(b) (4)	
Adventitious Agents			
Bacterial Endotoxin	Endotoxin (LAL) (Ph. Eur. 2.6.14, USP <85>, JP 4.01)	(b) (4)	
Sterility	Sterility ^c (Ph. Eur. 2.6.1, USP <71>, JP 4.06)	No Growth Detected	
Container Closure Integrity	(b) (4)	Pass	

- a. All assays performed on stability unless otherwise noted.
b. In accordance with Ph. Eur. 2.2.35, with minor difference in instrument calibration
c. Assay not performed on stability.
d. Acceptance criteria values reflect viscosity correction. See [Section 3.2 P.5.6.8](#) for detailed explanation.
e. (b) (4)

(b) (4)

Abbreviations: LNP = Lipid nanoparticles; CAD = charged aerosol detector; RT-PCR = reverse transcription polymerase chain reaction; FACS = fluorescence activated cell sorter; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amoebocyte lysate; EU = endotoxin unit

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