3.2.P.8.2. POST-APPROVAL STABILITY PROTOCOL AND STABILITY COMMITMENT

The commercial shelf life of the drug product will be established based on the ICH stability studies that are being carried out per protocols detailed in Section 3.2.P.8.1 Stability Summary and Conclusions.

Post-approval, a minimum of one lot of BNT162b2 drug product will be enrolled in the commercial stability program at the long term storage condition of -90 to -60 °C each year that drug product is manufactured. The protocol is provided in Table 3.2.P.8.2-1 for the long term storage conditions of -90 to -60°C.

Table 3.2.P.8.2-1. Post-Approval Commercial Stability Protocol for Drug Product Stored at -90 to -60 °C

Analytical Procedure/ Quality Attribute		**Test Intervals (Months)[a]**
Appearance (Visible)		0, 6, 12, 18, 24
Appearance (Visible Particulates)		
pH		
Subvisible Particulate Matter		
Dynamic Light Scattering (DLS)	LNP Size	
	LNP Polydispersity	
Fluorescense Assay	RNA Encapsulation	
	RNA Content	
HPLC-CAD	ALC-0315 Content	
	ALC-0159 Content	
	DSPC Content	
	Cholesterol Content	
Cell-based Flow Cytometry	In Vitro Expression	
Capillary Gel Electrophoresis	RNA Integrity	
Container Closure Integrity Test		Annually through end of shelf life
Sterility		0, End of shelf life
Endotoxin		

a. Additional test intervals may be included for the purpose of extending expiry.
Abbreviations: LNP = Lipid Nanoparticle

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