3.2.P.8.3. STABILITY DATA – PHOTOSTABILITY

Data from one stability study on a BNT162b2 process validation drug product subjected to ICH photostability conditions is presented. Drug product vials were exposed to a light source that provides an overall illumination of not less than 1.2 million lux hours and an integrated ultraviolet energy of not less than 200 watt hours/m^2, per ICH Q1B. Dark control vials were wrapped in aluminum foil to prevent exposure to light. All samples were stored inverted at 2 to 8 °C for the duration of the study, as it is not feasible to maintain the samples at the intended storage condition of -90 to -60 °C for this study and the 2 to 8 °C condition is considered a worse case exposure condition. Testing was performed according to Table 3.2.P.8.3-1.

Table 3.2.P.8.3-1. Stability Data for Drug Product Lot EL7834 Stored at Photostability Conditions

Time (months)	Appearance		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Appearance (Visible)		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria [ab]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)			
With Light Protection	WOS	Meets (b) (4)	(b) (4)				
Without Light Protection	WOS	Meets (b) (4)					

Time (months)	HPLC-CAD				Cell-based (b)	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In vitro Expression	RNA Integrity
Acceptance Criteria [ab]	(b) (4)					
With Light Protection	(b) (4)					
Without Light Protection						

a. 1.2 million lux hours of light and 200 watt hours/m^2 of near ultraviolet light at 5 ± 3 °C.
b. Acceptance criteria in place at time of testing.
WOS = White to off-white suspension, (b) (4), S = To be Scheduled, LNP = Lipid Nanoparticle