

3.2.P.8.3. STABILITY DATA – PHOTOSTABILITY – TRIS/SUCROSE DRUG PRODUCT

Stability data from a single BNT162b2 Tris/Sucrose 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/m², 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 procedure and results are provided in [Table 3.2.P.8.3-1](#).

Table 3.2.P.8.3-1. Stability Data for Tris/Sucrose MDV Drug Product Lot EW4564 Tested for Photostability

Test Articles	Appearance		pH	Subvisible Particles ^c	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Appearance (Visible)			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^{a,b}	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
With Light Protection	WOS	Meets (EFVP)	7.3					
Without Light Protection	WOS	Meets (EFVP)	7.3					

Test Articles	HPLC-CAD				Cell-based FACS		Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In vitro Expression		
Acceptance Criteria ^{a,b}	4.2 1st ind						4.2 1st ind
With Light Protection							
Without Light Protection							

a. .2 million lux hours of light and 200 watt hours/m² of near ultraviolet light at 5 ± 3 °C.

b. Acceptance criteria in place at time of testing.

c. Subvisible particles are reported per container.

d. Assay run for information only.

WOS = White to off-white suspension, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle