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## 3.2.P.8.3. STABILITY DATA - THERMAL - STRESS AND CYCLING

Data from stability studies on BNT162b2 drug product lots stored at the thermal stress conditions of  $25 \pm 2$  °C/60  $\pm$  5% RH and  $30 \pm 2$  °C/65  $\pm$  5% RH, as well as thermal cycling studies, are presented for emergency supply and process performance qualification lots manufactured by Polymun Scientific (with fill and finish at Pfizer, Puurs), mibe (with fill and finish at Pfizer, Puurs), Pfizer, Puurs and Pfizer, Kalamazoo, MI.

Additionally, data from supportive stability studies for one clinical BNT162b2 drug product lot stored at the thermal stress condition of  $25 \pm 2$  °C and manufactured by Polymun Scientific is also presented.

All studies are listed in Table 3.2.P.8.3-1. Results will be provided in Table 3.2.P.8.3-2 through Table 3.2.P.8.3-22.

Table 3.2.P.8.3-1. Summary of Drug Product Thermal Stability Studies

Lot Number	Drug Product Batch Use	Stability Start Date	Study Type	Storage Condition	Stability Data Presented	Data Table Location
EL8723 (Pfizer, Puurs)	Stability, Clinical, Emergency Supply <sup>a</sup> ,	January 2021	Thermal Stress	$25 \pm 2$ °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-2
	Process performance qualification		Thermal Stress	$30 \pm 2$ °C/65 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-3
		(TC Study: February 2021)	Thermal Cycling: Ultra froze 5 °C for 4 weeks and then m weeks. Samples will be pulle throughout protocol.	oved to 2 to 8°C for 12	8 weeks (On-going)	Table 3.2.P.8.3-19
EL3248 (Pfizer, Kalamazoo,	Stability, Clinical, Emergency Supply <sup>a</sup> ,	December 2020	Thermal Stress	$25 \pm 2$ °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-4
Line()	Process performance qualification		Thermal Stress	$30 \pm 2$ °C/65 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-5
EN1195 (mibe/Pfizer, Puurs)	Stability, Emergency Supply <sup>a</sup> , Process performance qualification	February 2021	Thermal Cycling: Ultra froze 5 °C for 4 weeks and then m weeks. Samples will be pulle throughout protocol.	oved to 2 to 8°C for 12	6 weeks (On-going)	Table 3.2.P.8.3-17
EL9266 (Pfizer, Kalamazoo, Line (b)	Stability, Emergency Supply <sup>a</sup> , Process performance qualification	February 2021	Thermal Cycling: Ultra froze 5 °C for 4 weeks and then m weeks. Samples will be pulle throughout protocol.	oved to 2 to 8°C for 12	8 weeks (On-going)	Table 3.2.P.8.3-18
EL3249 (Pfizer, Kalamazoo, Line (b)	Stability, Clinical, Emergency Supply <sup>a</sup> , Process performance qualification	January 2021	2 weeks at $-20 \pm 5$ °C, 4 we at $25 \pm 2$ °C/60 $\pm 5$ % RH.	Thermal Cycling: 1 week at -90 to -60°C , followed by 2 weeks at -20 $\pm$ 5 °C, 4 weeks at 2 to 8°C and 1 week at 25 $\pm$ 2 °C/60 $\pm$ 5% RH.		Table 3.2.P.8.3-20
EK4242 (mibe/Pfizer, Puurs)	Stability, Emergency Supply <sup>a</sup> , Process performance qualification	January 2021	Thermal Cycling: 1 week at -90 to -60°C followed by 4 weeks at 2 to 8°C		5 weeks (Complete)	Table 3.2.P.8.3-21
EL7834 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply <sup>a</sup> , Process performance qualification	January 2021	Thermal Cycling: 1 week at weeks at $-20 \pm 5$ °C and ther week at $25 \pm 2$ °C/60 $\pm 5\%$ I	4 weeks at 2 to 8°C. and 1	10 weeks (Complete)	Table 3.2.P.8.3-22

**Summary of Drug Product Thermal Stability Studies** Table 3.2.P.8.3-1.

Lot Number	Drug Product Batch Use	Stability Start Date	Study Type	Storage Condition	Stability Data Presented	Data Table Location
EH9899 Pfizer, Kalamazoo)	Stability, Emergency Supply <sup>a</sup>	November 2020	Thermal Stress	25 ± 2 °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-6
EJ1688 (mibe/Pfizer, Puurs)	Stability, Emergency Supply <sup>a</sup>	November 2020	Thermal Stress	$25 \pm 2$ °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-7
EK1768 (Polymun	Stability, Emergency Supply <sup>a</sup> , Clinical	November 2020	Thermal Stress	$25 \pm 2$ °C/60 $\pm 5$ % RH	1 month (Complete)	Table 3.2.P.8.3-8
Scientific/Pfizer, Puurs	inventory		Thermal Cycling: 2 weeks 4 weeks at -20 ± 5 °C and Samples will be pulled for throughout protocol.		14 weeks (Complete)	Table 3.2.P.8.3-15
EJ1686 (Polymun	Stability, Emergency Supply <sup>a</sup> , Clinical	November 2020	Thermal Stress	$25 \pm 2$ °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-9
Scientific/Pfizer, Puurs	inventory		Thermal Cycling: 2 weeks 4 weeks at -20 ± 5 °C and Samples will be pulled for throughout protocol.		14 weeks (Complete)	Table 3.2.P.8.3-16
EJ1685 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply <sup>a</sup> , Clinical inventory	November 2020	Thermal Stress	25 ± 2 °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-10
EJ0553 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply <sup>a</sup> , Clinical inventory	November 2020	Thermal Stress	25 ± 2 °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-11
EE8493 (Polymun	Stability, Emergency Supply <sup>a</sup> , Clinical	September 2020	Thermal Stress	$25 \pm 2$ °C/60 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-12
Scientific/Pfizer, Puurs)	inventory		Thermal Stress	30 ± 2 °C/65 ± 5% RH	1 month (Complete)	Table 3.2.P.8.3-13
BCV40420-A (Polymun Scientific)	Stability, Clinical	May 2020	Thermal Stress	25 ± 2 °C	4 months (complete)	Table 3.2.P.8.3-14

a. Emergency supply designation applies to US market.

b. A minimum of one PPQ lot will be enrolled in thermal stress and thermal cycling stability programs compliant with ICH Guidelines and further information on lot numbers, manufacture, stability enrollment and available data will be provided in the future.

TBD = To Be Determined

Table 3.2.P.8.3-2. Stability Data for Drug Product PPQ Lot EL8723 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical	Appearance		pН	Dynamic Light So	cattering (DLS)	Fluor	escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	$7.4 \pm 0.5$	(b) (4)			
0 b	WOS	Meets (b)	(b) (4)				
1W	WOS	Meets (b)					
2W	WOS	Meets (b)					
1M	WOS	Meets (b)					

Analytical Procedure/Quality		HPLC	Cell-based Flow Cytometry	Capillary Gel Electrophoresis		
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
0	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in place at time of testing.

b. T=0 testing performed for this lot (release values not utilized.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector, WOS = White to off-white suspension

Table 3.2.P.8.3-3. Stability Data for Drug Product PPQ Lot EL8723 Stored at  $30 \pm 2$  °C/65  $\pm 5$ % RH

Analytical	Appearance		pН	Dynamic Light Sc	cattering (DLS)	Fluor	escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates	-	LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles		(b) (4)			
0 <sub>p</sub>	WOS	Meets(b) (4)	(b) (4)				
1W	WOS	Meets (b)					
2W	WOS	Meets (b)					
1M	WOS	Meets (b)					

Analytical Procedure/Quality		HPLC	Cell-based Flow Cytometry	Capillary Gel Electrophoresis		
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	<b>Cholesterol Content</b>	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
0	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in

b. T=0 testing performed for this lot (release values not utilized.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector, WOS = White to off-white suspension

Table 3.2.P.8.3-4. Stability Data for Drug Product PPQ Lot EL3248 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical	Appeara	pН	Dynamic Light	Scattering (DLS)	Fluorescence Assay		
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	$7.4 \pm 0.5$	(b) (4)			
0	WOS	Meets (b)	(b) (4)				
1W	WOS	Meets (b)	_				
2W	WOS	Meets (b)					
3W	WOS	Meets (b)					
1M	WOS	Meets (b)					

Analytical		HPLC	C-CAD		Cell-based Flow Cytometry	Capillary Gel
Procedure/Quality Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	Electrophoresis RNA Integrity
Timepoint / Acceptance	(b) (4)	Tibe visy content	DSI C CONCIL	Choicster or Content	III VILLO EXPICACION	Tu (11 Integrity
Criteria <sup>a</sup>						
0	(b) (4)					
1W						
2W						
3W						
1M						

a. Acceptance criteria in place at time of testing.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector, WOS = White to off-white suspension

Table 3.2.P.8.3-5. Stability Data for Drug Product PPQ Lot EL3248 Stored at  $30 \pm 2$  °C/65  $\pm 5$ % RH

Analytical	Appearance		pН	Dynamic Light S	Scattering (DLS)	Fluore	scence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	$7.4 \pm 0.5$	(b) (4)			
0	WOS	Meets (b)	(b) (4)				
1W	WOS	Meets (b)					
2W	WOS	Meets (b)					
3W	WOS	Meets (b)					
1M	WOS	Meets (b)					

Analytical		HPLC	C-CAD		Cell-based Flow Cytometry	Capillary Gel
Procedure/Quality					Electrophoresis	
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	<b>Cholesterol Content</b>	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
0	(b) (4)					
1 W						
2W						
3W						
1M						

a. Acceptance criteria in place at time of testing.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector, WOS = White to off-white suspension

Table 3.2.P.8.3-6. Stability Data for Drug Product Emergency Supply Batch EH9899 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical	Appeara	Appearance			cattering (DLS)	Fluorescence Assay	
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)			
0 р	White to off-white suspension	(b)	(b) (4)				
1W	White to off-white suspension	(b)					
2W	White to off-white suspension	(b)					
1M	White to off-white suspension	(b)					

Analytical Procedure/Quality		HPLC	C-CAD	Cell-based Flow Cytometry	Capillary Gel Electrophoresis	
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
0	(b) (4)					
1 W						
2W						
1M						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 1 week time point.

; LNP = Lipid Nanoparticle; HPLC-CAD

b. T=0 testing performed for this lot (release values not utilized.

c. Result invalidated and not repeated as 1 month time point was pulled for testing.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>=</sup> high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-7. Stability Data for Drug Product Emergency Supply Batch EJ1688 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical	Appear	pН	Dynamic Light Scattering (DLS)		Fluorescence Assay		
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance	White to off-white suspension	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Criteria <sup>a</sup>		off-white opaque,					
		amorphous particles					
0	White to off-white suspension	(b)	(b) (4)				
1 W	White to off-white suspension	(b)					
2W	White to off-white suspension	(b)					
1M	White to off-white suspension	Meets (b)					

Analytical		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel
Procedure/Quality						Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>	(1.) (4)					
0	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 1 month time point.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-8. Stability Data for Drug Product Emergency Supply Batch EK1768 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical	, 11		pН	Dynamic Light Scattering (DLS)		Fluor	escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance	White to off-white suspension	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Criteria <sup>a</sup>		off-white opaque,					
		amorphous particles					
0	White to off-white suspension	(b)	(b) (4)				
1 W	White to off-white suspension	Meets (b)					
2W	White to off-white suspension	Meets (b)					
1M	White to off-white suspension	Meets (b)					

Analytical		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel
Procedure/Quality						Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>	(1.) (4)					
0	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 1 week time point.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-9. Stability Data for Drug Product Emergency Supply Batch EJ1686 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical	Appearance		pН	Dynamic Light So	Dynamic Light Scattering (DLS)		escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint /	White to off-white	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Acceptance Criteriaa	suspension	off-white opaque,					
		amorphous particles					
$0_{\rm p}$	White to off-white suspension	(b)	(b) (4)				
1W	White to off-white suspension	Meets (b)					
2W	White to off-white suspension	Meets (b)					
1M	White to off-white suspension	Meets (b)					

Analytical Procedure/Quality		HPLC	-CAD	Cell-based Flow Cytometry	Capillary Gel Electrophoresis	
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint /	(b) (4)			Content		
Acceptance Criteria <sup>a</sup>	(1.) (4)					
$0_{\rm p}$	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 1 week time point. b. T=0 testing performed for this lot (release values not utilized.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-10. Stability Data for Drug Product Emergency Supply Batch EJ1685 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Analytical Appearan Procedure/Quality Attribute Appearance (Visual)		ance	pН	Dynamic Light Sc	cattering (DLS)	Fluorescence Assay	
		Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance	White to off-white suspension	May contain white to	$7.4 \pm 0.5$	(b) (4)	•		
Criteria <sup>a</sup>		off-white opaque,					
		amorphous particles					
0	White to off-white suspension	(b)	(b) (4)				
1W	White to off-white suspension	(b)					
2W	White to off-white suspension	Meets (b)					
1M	White to off-white suspension	Meets (b)					

Analytical Procedure/Quality		HPLC	-CAD	Cell-based Flow Cytometry	Capillary Gel Electrophoresis	
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
0	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 2 week time point.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-11. Stability Data for Drug Product Emergency Supply Batch EJ0553 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

		ance	nce pH Dynan		Dynamic Light Scattering (DLS)		Fluorescence Assay	
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content	
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles		(b) (4)				
0	White to off-white suspension	(b)	(b) (4)					
1W	White to off-white suspension	(b)						
2W	White to off-white suspension	(b)						
1M	White to off-white suspension	(b)						

Analytical Procedure/Quality		HPLC-C	Cell-based Flow Cytometry	Capillary Gel Electrophoresis		
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
0	(b) (4)					
1W						
2W						
1M						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 1 month time point.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4)

<sup>;</sup> LNP = Lipid Nanoparticle; HPLC-CAD

<sup>=</sup> high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-12. Stability Data for Drug Product EE8493 Stored at  $25 \pm 2$  °C/60  $\pm 5$ % RH

Time	Appearance		pН	Dynamic Light	Dynamic Light Scattering (DLS)		ice Assay
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria <sup>a</sup>	White to off-white suspension	(b)	7.4 ± 0.5	(b) (4)			
0	White to off-white suspension	(b)	(b) (4)				
2W	White to off-white suspension	(b)					
1M	White to off-white suspension	(b)					

Time		HPLC	Cell-based (b) (4)	Capillary Gel Electrophoresis		
	ALC-0315 Content	ALC-0159 Content	<b>DSPC Content</b>	<b>Cholesterol Content</b>	In Vitro Expression	RNA Integrity
Acceptance Criteria <sup>a</sup>	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	% Cells Positive	(b) (4)
0 2W 1M	(b) (4)					

<sup>a. Acceptance criteria in place at time of testing.
b. Original result investigated and invalidated with no result being reported.
W = Week, M = Month, S = To be Scheduled, (b) (4)</sup> 

<sup>,</sup> LNP = Lipid Nanoparticle, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-13. Stability Data for Drug Product EE8493 Stored at  $30 \pm 2$  °C/65  $\pm 5\%$  RH

Time	Appearance		pН	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Bolydian ansity	RNA Encongrelation	RNA Content
				(1.) (4)	Polydispersity	Encapsulation	
Acceptance	White to off-white suspension	(b)	$7.4 \pm 0.5$	(b) (4)			
Criteria <sup>a</sup>	_						
0	White to off-white suspension	(b)	(b) (4)				
2W	White to off-white suspension	(b)					
1M	White to off-white suspension	(b)					

Time		HPLC-		Cell-based (b) (4)	Capillary Gel Electrophoresis	
	ALC-0315 Content	ALC-0159 Content	DSPC Content	<b>Cholesterol Content</b>	In Vitro Expression	RNA Integrity
Acceptance Criteria <sup>a</sup>	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	% Cells Positive	(b) (4)
0 2W 1M	(b) (4)					

<sup>a. Acceptance criteria in place at time of testing.
b. Original result investigated and invalidated with no result reported.
W = Week, M = Month, S = To be Scheduled, (b) (4)</sup> 

<sup>,</sup> LNP = Lipid Nanoparticle, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-14. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40420-A Stored at 25 ± 2 °C

Time (Months)	Appearance	pН	LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria <sup>a</sup>	White to off-white suspension/Free from observable particles	7.4 ± 0.5	(b) (4)			
0	Pass	(b) (4)	(b) (4)			
0.5	Pass	NS				
1	Pass	NS				
2	Pass	NS				
3	Pass	(b) (4)				
4	Pass	NS				

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	(b) (4)
Criteria		, , ,	, , , ,		
0	(b) (4)				
0.5					
1					
2					
3					
4					

a. Acceptance criteria in place at time of testing.
 S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle

Table 3.2.P.8.3-15. Thermal Cycling Stability Data for Drug Product Emergency Supply Batch EK1768

Analytical	Appeara	ance	pН	Dynamic Light S	Dynamic Light Scattering (DLS)		scence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	$7.4 \pm 0.5$	(b) (4)			
Placed @ -90 to -60°C (fe	or 2 weeks)						
0	WOS	(b)	(b) (4)				
Samples pulled for 2W to	esting. Inventory moved to -20	± 5°C (for 4 weeks)					
2W	WOS	Meets (b) (4)	(b) (4)				
4W	WOS	Meets (b) (4)					
Samples pulled for 6W to	esting. Inventory moved to 2 to	8 °C for remainder of stud					
6W	WOS	Meets (b) (4)	(b) (4)				
8W	WOS	Meets (b) (4)	_				
10W	WOS	Meets (b)					
12W	WOS	Meets (b) (4)					
14W	WOS	Meets (b) (4)					

Analytical Procedure/Quality		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance	(b) (4)					
Criteria <sup>a</sup>						
Placed @ -90 to -60°C (fo						
0	(b) (4)					
Samples pulled for 2W te	sting. Inventory moved	to $-20 \pm 5$ °C (for 4 wee	ks)			
2W	(b) (4)					
4W						
Samples pulled for 6W te		to 2 to 8 °C for remaine	der of study			
6W	(b) (4)					
8W						
10W						
12W						
14W						

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 8 week time point. W = Week, S = To be Scheduled, (b) (4) , LNP = Lipid Nanoparticle, HPLC-CAI charged aerosol detector, WOS = White to off-white suspension

<sup>,</sup> LNP = Lipid Nanoparticle, HPLC-CAD = high performance liquid chromatography-

Table 3.2.P.8.3-16. Thermal Cycling Stability Data for Drug Product Emergency Supply Batch EJ1686

Analytical	Appear	ance	pН	Dynamic Light So	cattering (DLS)	Fluore	scence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint /	White to off-white	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Acceptance Criteria <sup>a</sup>	suspension	off-white opaque,					
		amorphous particles					
Placed @ -90 to -60°C (fo	or 2 weeks)						
0 <sub>p</sub>	WOS	(b)	(b) (4)				
Samples pulled for 2W te	sting. Inventory moved to -20	± 5°C (for 4 weeks)					
2W	WOS	Meets (b) (4)	(b) (4)				
4W	WOS	Meets (b) (4)	-				
Samples pulled for 6W te	sting. Inventory moved to 2 to	8 °C for remainder of stud	dy				
6W	WOS	Meets (b) (4)	(b) (4)				
8W	WOS	Meets (b) (4)	-				
10W	WOS	Meets (b) (4)					
12W	WOS	Meets (b) (4)					
14W	WOS	Meets (b) (4)					

Analytical Procedure/Quality		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel Electrophoresis				
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity				
Timepoint /	(b) (4)									
Acceptance Criteriaa										
Placed @ -90 to -60°C (fe	or 2 weeks)									
0 <sub>p</sub>	(b) (4)	(4)								
Samples pulled for 2W te	sting. Inventory moved	to $-20 \pm 5$ °C (for 4 week	eks)							
2W	(b) (4)									
4W										
Samples pulled for 6W te		to 2 to 8 °C for remain	der of study							
6W	(b) (4)									
8W										
10W										
12W										
14W										

Table 3.2.P.8.3-16. Thermal Cycling Stability Data for Drug Product Emergency Supply Batch EJ1686

Analytical	Appearance		pН	Dynamic Light Scattering (DLS)		Fluorescence Assay	
Procedure/Quality	Abbearance (visual)   visible rarticulates			LNP Size	LNP	RNA	RNA Content
Attribute	1 special mass ( 1 sams)				Polydispersity	Encapsulation	

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 8 week time point.

b. Initial data (t0) are not from release testing. Analysis for t0 were repeated for this study.

W = Week, S = To be Scheduled, (b) (4)

, LNP =

Table 3.2.P.8.3-17. Thermal Cycling Stability Data for Drug Product PPQ Lot EN1195

Analytical	Appear	ance	pН	Dynamic Light	Scattering (DLS)	Fluores	cence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint /	White to off-white	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Acceptance Criteria <sup>a</sup>	suspension	off-white opaque,					
		amorphous particles					
Placed @ $-20 \pm 5$ °C (for 4	weeks)						
0	WOS	Meets (b) (4)	(b) (4)				
2W	WOS	Meets (b) (4)	_				
4W	WOS	Meets (b) (4)					
Samples pulled for 4W tes	sting. Inventory moved to 2 to	8 °C for remainder of stud	dy				
6W	WOS	Meets (b) (4)	(b) (4)				
8W	S	S	S	S	S	S	S
10W	S	S	S	S	S	S	S
12W	S	S	S	S	S	S	S
14W	S	S	S	S	S	S	S
16W	S	S	S	S	S	S	S

Analytical Procedure/Quality		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint /	(b) (4)					
Acceptance Criteria <sup>a</sup>						
Placed @ $-20 \pm 5$ °C (for $0$	4 weeks)					
0	(b) (4)					
2W						
4W						
Samples pulled for 4W to	esting. Inventory moved	to 2 to 8 °C for remain	der of study			
6W	(b) (4)					
8W	S	S	S	S	S	S
10W	S	S	S	S	S	S
12W	S	S	S	S	S	S
14W	S	S	S	S	S	S
16W	S	S	S	S	S	S

Table 3.2.P.8.3-17. Thermal Cycling Stability Data for Drug Product PPQ Lot EN1195

Analytical	Appearance		pН	Dynamic Light Sc	cattering (DLS)	Fluorescence Assay	
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
					rolyuispersity	Encapsulation	

a. Acceptance criteria in place at time of testing. W = Week, S = To be Scheduled, (b) (4)

, LNP = Lipid Nanoparticle, HPLC-CAD = high performance liquid chromatography-

Table 3.2.P.8.3-18. Thermal Cycling Stability Data for Drug Product PPQ Lot EL9266

Analytical	Appear	ance	pН	Dynamic Light Sc	cattering (DLS)	Fluore	escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	$7.4 \pm 0.5$	(b) (4)			
Placed @ $-20 \pm 5$ °C (for 4	weeks)						
$0_{\rm p}$	WOS	Meets (b) (4)	(b) (4)				
2W	WOS	Meets (b) (4)					
4W	WOS	Meets (b) (4)					
Samples pulled for 4W tes	sting. Inventory moved to 2 to		dy				
6W	WOS		(b) (4)				
8W	WOS	Meets (b) (4)					
10W	S	S	S	S	S	S	S
12W	S	S	S	S	S	S	S
14W	S	S	S	S	S	S	S
16W	S	S	S	S	S	S	S

Analytical Procedure/Quality		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint /	(b) (4)					
Acceptance Criteria <sup>a</sup>						
Placed @ $-20 \pm 5$ °C (for 4	4 weeks)					
$0_{\rm p}$	(b) (4)					
2W						
4W						
Samples pulled for 4W te		to 2 to 8 °C for remain	der of study			
6W	(b) (4)					
8W						
10W	S	S	S	S	S	S
12W	S	S	S	S	S	S
14W	S	S	S	S	S	S
16W	S	S	S	S	S	S

Table 3.2.P.8.3-18. Thermal Cycling Stability Data for Drug Product PPQ Lot EL9266

Analytical	Appearance		pН	Dynamic Light Sc	cattering (DLS)	Fluorescence Assay	
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
					rolyuispersity	Encapsulation	

a. Acceptance criteria in place at time of testing.
b. Initial data (t0) are not from release testing. Analysis for t0 were repeated for this study.
W = Week, S = To be Scheduled, (b) (4)
, LNP =

Table 3.2.P.8.3-19. Thermal Cycling Stability Data for Drug Product PPQ Lot EL8723

Analytical	Appear	ance	pН	Dynamic Light S	cattering (DLS)	Fluore	scence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria <sup>a</sup>	White to off-white suspension	May contain white to off-white opaque, amorphous particles	$7.4 \pm 0.5$	(b) (4)			
Placed @ $-20 \pm 5$ °C (for $-20 \pm 5$ °C)	weeks)						
$0_{p}$	WOS	Meets (b) (4)	(b) (4)				
2W	WOS	Meets (b) (4)					
4W	WOS	Meets (b) (4)					
Samples pulled for 4W tes	sting. Inventory moved to 2 to		dy				
6W	WOS		(b) (4)				
8W	WOS	Meets (b) (4)					
10W	S	S	S	S	S	S	S
12W	S	S	S	S	S	S	S
14W	S	S	S	S	S	S	S
16W	S	S	S	S	S	S	S

Analytical		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel
Procedure/Quality	AT C 0215 C	AT C 0450 C	DODG G	CL 1 / 1	T 771	Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol	In Vitro Expression	RNA Integrity
				Content		
Timepoint /	(b) (4)					
Acceptance Criteria <sup>a</sup>						
Placed @ $-20 \pm 5$ °C (for $0$ )	4 weeks)					
$0_{\rm p}$	(b) (4)					
2W						
4W						
Samples pulled for 4W te		to 2 to 8 °C for remain	der of study			
6W	(b) (4)					
8W						
10W	S	S	S	S	S	S
12W	S	S	S	S	S	S
14W	S	S	S	S	S	S
16W	S	S	S	S	S	S

Table 3.2.P.8.3-19. Thermal Cycling Stability Data for Drug Product PPQ Lot EL8723

Analytical	Appearance		pН	Dynamic Light Sc	cattering (DLS)	Fluore	escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
					1 oryuispersity	Encapsulation	

a. Acceptance criteria in place at time of testing.
b. Initial data (t0) are not from release testing. Analysis for t0 were repeated for this study.
W = Week, S = To be Scheduled, (b) (4), LNP =

Table 3.2.P.8.3-20. Thermal Cycling Stability Data for Drug Product PPQ Lot EL3249

Analytical	Appear	ance	pН	Dynamic Light	Scattering (DLS)	Fluores	cence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint /	White to off-white	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Acceptance Criteria <sup>a</sup>	suspension	off-white opaque,					
		amorphous particles					
Placed @ -90 to -60 °C (f	for 1 week)						
0	WOS	Meets (b) (4)	(b) (4)				
At 1W, inventory moved	to $-20 \pm 5$ °C (for 2 weeks)						
3W	WOS	Meets (b) (4)	(b) (4)				
Samples pulled for 3W te	sting. Inventory moved to 2 to						
4W	WOS	Meets (b) (4)	(b) (4)				
5W	WOS	Meets (b) (4)					
6W	WOS	Meets (b) (4)					
7W	WOS	Meets (b) (4)					
Samples pulled for 7W te	sting. Inventory moved to 25						
8W	WOS	Meets (b) (4)	(b) (4)				

Analytical Procedure/Quality		HPLC	-CAD		Cell-based Flow Cytometry	Capillary Gel Electrophoresis
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint /	(b) (4)					
Acceptance Criteria <sup>a</sup>						
Placed @ -90 to -60 °C (1	for 1 week)					
0	(b) (4)					
At 1W, inventory moved	to $-20 \pm 5$ °C (for 2 weed) (b) (4)	eks)				
3W Samples pulled for 3W te		to 2 to 8 °C (for 4 week	(s)			
	(b) (4)	2 00 0 0 (101 1 1100)				
5W						
6W						
7W						
Samples pulled for 7W te		to $25 \pm 2$ °C/60 $\pm 5\%$ F	RH (for 1 week)			
8W	[(b) (4)					

Table 3.2.P.8.3-20. Thermal Cycling Stability Data for Drug Product PPQ Lot EL3249

Analytical Appearance		pН	Dynamic Light So	cattering (DLS)	ttering (DLS) Fluorescence Assa		
Procedure/Quality	Appearance (Visual)	Visible Particulates		LNP Size	LNP	RNA	RNA Content
Attribute					Polydispersity	Encapsulation	

a. Acceptance criteria in place at time of testing. W = Week, S = To be Scheduled, (b) (4)

, LNP = Lipid Nanoparticle, HPLC-CAD = high performance liquid chromatography-

Table 3.2.P.8.3-21. Thermal Cycling Stability Data for Drug Product PPQ Lot EK4242

Analytical	• • • • • • • • • • • • • • • • • • • •		pН	Dynamic Light So	cattering (DLS)	Fluore	escence Assay
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint /	White to off-white	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Acceptance Criteria <sup>a</sup>	suspension	off-white opaque, amorphous particles					
Placed @ -90 to -60 °C (f	or 1 week)		<i>(</i> , ) <i>(</i> , )				
0	WOS	Meets (b) (4)	(b) (4)				
At 1W, inventory moved	to 2 to 8 °C for remainder of s						
2W	WOS	Meets (b) (4)	(b) (4)				
3W	WOS	Meets (b) (4)					
4W	WOS	Meets (b) (4)					
5W	WOS	Meets (b) (4)					

Analytical Procedure/Quality	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis			
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint /	(b) (4)								
Acceptance Criteria <sup>a</sup>									
Placed @ -90 to -60 °C (f	or 1 week)								
0	(b) (4)								
At 1W, inventory moved	At 1W, inventory moved to 2 to 8 °C for remainder of study (4 weeks)								
2W	(b) (4)								
3W									
4W									
5W									

a. Acceptance criteria in place at time of testing.
b. Initial data (t0) are not from release testing. Analysis for t0 were repeated for this study.
W = Week, S = To be Scheduled, (b) (4), LNP = , LNP = Lipid Nanoparticle, HPLC-CAD = high performance liquid chromatographycharged aerosol detector, WOS = White to off-white suspension

Table 3.2.P.8.3-22. Thermal Cycling Stability Data for Drug Product PPQ Lot EL7834

Analytical Appear		ance	pH Dynamic Light Scattering (DLS) Flo		Fluore	scence Assay	
Procedure/Quality Attribute	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint /	White to off-white	May contain white to	$7.4 \pm 0.5$	(b) (4)			
Acceptance Criteria <sup>a</sup>	suspension	off-white opaque, amorphous particles					
Placed @ -90 to -60 °C (f	for 1 week)			•			
0	WOS	Meets (b) (4)	(b) (4)				
At 1W, inventory moved		(1 ) (4)					
3W	WOS	Meets (b) (4)	(b) (4)				
5W	WOS	Meets (b) (4)					
Samples pulled for 5W testing. Inventory moved to 2 to 8 °C (for 4 weeks)		(1.) (4)					
6W	WOS	Meets (b) (4)	(b) (4)				
7W	WOS	Meets (b) (4)					
8W	WOS	Meets (b) (4)					
9W	WOS	Meets (b) (4)					
Samples pulled for 7W testing. Inventory moved to $25 \pm 2$ °C/60 $\pm 5$ % RH (for 1 week)							
10W	WOS	Meets (b) (4)	(b) (4)				

Analytical Procedure/Quality	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis			
Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint /	(b) (4)								
Acceptance Criteria <sup>a</sup>									
Placed @ -90 to -60 °C (1									
0	(b) (4)								
At 1W, inventory moved	At 1W, inventory moved to $-20 \pm 5$ °C (for 4 weeks)								
3W	(b) (4)								
5W									
Samples pulled for 5W testing, Inventory moved to 2 to 8 °C (for 4 weeks)									
6W	(b) (4)								
7W									
8W									
9W									
Samples pulled for 7W testing. Inventory moved to $25 \pm 2$ °C/60 $\pm 5$ % RH (for 1 week)									
10W	(b) (4)								

Table 3.2.P.8.3-22. Thermal Cycling Stability Data for Drug Product PPQ Lot EL7834

Analytical	Appearance		pН	Dynamic Light Scattering (DLS)		Fluorescence Assay	
Procedure/Quality	Appearance (Visual)	Visible Particulates		LNP Size	LNP	RNA	RNA Content
Attribute					Polydispersity	Encapsulation	

a. Acceptance criteria in place at time of testing.
b. Initial data (t0) are not from release testing. Analysis for t0 were repeated for this study.
W = Week, S = To be Scheduled, (b) (4)
, LNP =