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3.2.P.8.3. STABILITY DATA - LONG TERM

Data from stability studies on BNT162b2 drug product lots stored at the long term condition of -90 to -60 °C are presented for emergency supply lots and process performance qualification lots manufactured by multiple manufacturing and fill and finish sites.

Data from seven clinical and one non-clinical stability studies on drug product manufactured by Polymun Scientific are also being presented at the long term condition of -70 ± 10 °C.

All studies are listed in Table 3.2.P.8.3-1. Results are provided in Table 3.2.P.8.3-2 through Table 3.2.P.8.3-35 and in Figure 3.2.P.8.3-1 through Figure 3.2.P.8.3-10. All results, generated to date, met the acceptance criteria at the time of testing.

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

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Table Location
(BNT162b2)				
EN6199 (Pfizer, Kalamazoo, Line (b) (4))	Stability, Emergency Supply[a], Process performance qualification	February 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-2
EL3249 (Pfizer, Kalamazoo, Line (b) (4))	Stability, Clinical, Emergency Supply[a], Process performance qualification	December 2020	-90 to -60 °C Upright: 6 months	Table 3.2.P.8.3-3
			-90 to -60 °C Inverted: 6 months	Table 3.2.P.8.3-34
EL9267 (Pfizer, Kalamazoo, Line (b) (4)	Stability, Emergency Supply[a], Process performance qualification	January 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-4
EL3248 (Pfizer, Kalamazoo, Line (b) (4)	Stability, Clinical, Emergency Supply[a], Process performance qualification	December 2020	-90 to -60 °C Upright: 6 months	Table 3.2.P.8.3-5
			-90 to -60 °C Inverted: 6 months	Table 3.2.P.8.3-35
EM4965 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[a], Process performance qualification	February 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-6
EL7834 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply[a], Process performance qualification	December 2020	-90 to -60 °C Upright: 6 months	Table 3.2.P.8.3-8
			-90 to -60 °C Inverted: 6 months	Table 3.2.P.8.3-31
EN1195 (mibe/Pfizer, Puurs)	Stability, Emergency Supply[a], Process performance qualification	March 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-7
EK4242 (mibe/Pfizer, Puurs)	Stability, Emergency Supply[a], Process performance qualification	December 2020	-90 to -60 °C Upright: 6 months	Table 3.2.P.8.3-9
			-90 to -60 °C Inverted: 6 months	Table 3.2.P.8.3-32
EP2166 (Pfizer, Puurs)	Stability, Emergency Supply[a], Process performance qualification	January 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-10
EL8713 (Pfizer, Puurs)	Stability, Emergency Supply[a], Process performance qualification	January 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-11
EM6950 (Pfizer, Puurs)	Stability, Emergency Supply[a], Process performance qualification	January 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-12
EL8723 (Pfizer, Puurs)	Stability, Clinical, Emergency Supply[a], Process performance qualification	January 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-13
EL1491 (Pfizer, Puurs)	Stability, Emergency Supply[a], Clinical, Process performance qualification	December 2020	-90 to -60 °C Upright: 6 months	Table 3.2.P.8.3-14
			-90 to -60 °C Inverted: 6 months	Table 3.2.P.8.3-33

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

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Table Location
EH9899 Pfizer, Kalamazoo)	Stability, Emergency Supply[a]	November 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-15
EJ1688 (mibe/Pfizer, Puurs)	Stability, Emergency Supply[a]	November 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-16
EK1768 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply[a], Clinical inventory	November 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-17
EJ1686 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[a], Clinical inventory	November 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-18
EJ1685 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[a], Clinical inventory	November 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-19
EJ0553 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supplya, Clinical inventory	November 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-20
EE8493 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[a], Clinical inventory	September 2020	-90 to -60 °C: 9 months	Table 3.2.P.8.3-21
EE8492 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[a]	September 2020	-90 to -60 °C: 9 months	Table 3.2.P.8.3-4
EE3813[c] (Polymun Scientific/Pfizer, Puurs)	Stability, clinical	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-23
ED3938[d] (Polymun Scientific/Pfizer, Puurs)	Stability, clinical inventory	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-24
BCV40720-C (Polymun Scientific)	Stability, clinical	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-25
BCV40720-A (Polymun Scientific)	Stability, clinical	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-26
BCV40620-E (Polymun Scientific)	Stability, clinical	July 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-27
BCV40620-A (Polymun Scientific)	Stability, clinical	July 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-28
BCV40420-A (Polymun Scientific)	Stability, clinical	May 2020	-70 ± 10 °C: 12 months	Table 3.2.P.8.3-29
CoVVAC/270320 (Polymun Scientific)	Stability, non-clinical toxicology	March 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-30

a. Emergency supply designation applies to US market.
b. A minimum of three PPQ lot will be enrolled in stability programs compliant with ICH Guidelines and further information on lot numbers, manufacture, stability enrollment and available data will be provided in the future.
c. This lot number is equivalent to BCV40820-P
d. This lot number is equivalent to BCV40720-P.

Table 3.2.P.8.3-2. Stability Data for PPQ Drug Product EN6199 Stored at -90 to -60 °C (Pfizer, Kalamazoo)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
2W	WOFS	Meets		NS	(b) (4)			
1M	WOFS	Meets		NS				
2M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. Original result investigated and invalidated. Reference PR 5889739

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4) , NGD = No growth detected

Table 3.2.P.8.3-3. Stability Data for PPQ Drug Product EL3249 Upright Vials Stored at -90 to -60 °C (Pfizer, Kalamazoo)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4) , NGD = No growth detected

Table 3.2.P.8.3-4. Stability Data for PPQ Drug Product EL9267 Stored at -90 to -60 °C (Pfizer, Kalamazoo)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets (b) (4)	(b) (4)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS	(b) (4)			
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-4. Stability Data for PPQ Drug Product EL9267 Stored at -90 to -60 °C (Pfizer, Kalamazoo)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-5. Stability Data for PPQ Drug Product EL3248 Upright Vials Stored at -90 to -60 °C (Pfizer, Kalamazoo)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets (b) (4)	(b) (4)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4) , No growth detected

Table 3.2.P.8.3-6. Stability Data for PPQ Drug Product EM4965 Stored at -90 to -60 °C (Polymun/Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
2W	WOFS	Meets		NS	(b) (4)			
1M	WOFS	Meets		NS				
2M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-6. Stability Data for PPQ Drug Product EM4965 Stored at -90 to -60 °C (Polymun/Pfizer, Puurs)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-7. Stability Data for PPQ Drug Product EN1195 Stored at -90 to -60 °C (mibe/Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0 [c]	WOFS	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
2M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-7. Stability Data for PPQ Drug Product EN1195 Stored at -90 to -60 °C (mibe/Pfizer, Puurs)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. T=0 testing performed for this lot (release values not utilized)
d. Original result investigated and invalidated. Reference PR 5889739
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-8. Stability Data for PPQ Drug Product EL7834 Upright Vials Stored at -90 to -60 °C (Polymun/Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOS	Meets (b) (4)	(b) (4)	(b) (4)				
1M	WOS	Meets (b) (4)		NS	(b) (4)			
3M	WOS	Meets (b) (4)		NS				
6M	WOS	Meets (b) (4)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, WOS = White to off-white suspension, (b) (4), LNP = Lipid Nanoparticle

Table 3.2.P.8.3-9. Stability Data for PPQ Drug Product EK4242 Upright Vials Stored at -90 to -60 °C (mibe/Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOS	Meets	(b) (4)	(b) (4)				
1M	WOS	Meets		NS	(b) (4)			
3M	WOS	Meets		NS				
6M	WOS	Meets		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, WOS = White to off-white suspension, (b) (4), LNP = Lipid Nanoparticle

Table 3.2.P.8.3-10. Stability Data for PPQ Drug Product EP2166 Stored at -90 to -60 °C (Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets (b) (4)	(b) (4)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS	(b) (4)			
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-10. Stability Data for PPQ Drug Product EP2166 Stored at -90 to -60 °C (Pfizer, Puurs)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-11. Stability Data for PPQ Drug Product EL8713 Stored at -90 to -60 °C (Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets	(b) (4)					
2W	WOFS	Meets		NS				
1M	WOFS	Meets		NS				
2M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				
6M	S	S	S	S				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0									Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-11. Stability Data for PPQ Drug Product EL8713 Stored at -90 to -60 °C (Pfizer, Puurs)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-12. Stability Data for PPQ Drug Product EM6950 Stored at -90 to -60 °C (Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets (b) (4)	(b) (4)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS	(b) (4)			
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	ye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-12. Stability Data for PPQ Drug Product EM6950 Stored at -90 to -60 °C (Pfizer, Puurs)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-13. Stability Data for PPQ Drug Product EL8723 Stored at -90 to -60 °C (Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
2W	WOFS	Meets		NS	(b) (4)			
1M	WOFS	Meets		NS				
2M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-13. Stability Data for PPQ Drug Product EL8723 Stored at -90 to -60 °C (Pfizer, Puurs)

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-14. Stability Data for PPQ Drug Product EL1491 Upright Vials Stored at -90 to -60 °C (Pfizer, Puurs)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets (b) (4)	(b) (4)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-15. Stability Data for Drug Product Emergency Supply Lot EH9899 Stored at -90 to -60 °C

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0 [c]	WOFS	(b)	(b) (4)	(b) (4)				
1W	WOFS	(b)		NS	(b) (4)			
2W	WOFS	(b)		NS				
1M	WOFS	(b)		NS				
3M	WOFS	(b)		NS				
6M	WOFS	(b)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1W							NS	NS	NS
2W							NS	NS	NS
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

Table 3.2.P.8.3-15. Stability Data for Drug Product Emergency Supply Lot EH9899 Stored at -90 to -60 °C

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. 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, WOFS = White to off-white suspension, (b) (4) ,
LNP = Lipid Nanoparticle, NGD = No Growth Detected

Table 3.2.P.8.3-16. Stability Data for Drug Product Emergency Supply Lot EJ1688 Stored at -90 to -60 °C

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	(b)	(b) (4)	(b) (4)				
1W	WOFS	(b)		NS	(b) (4)			
2W	WOFS	(b)		NS				
1M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1W							NS	NS	NS
2W							NS	NS	NS
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, WOFS = White to off-white suspension, (b) (4), LNP = Lipid Nanoparticle, NGD = No Growth Detected

Table 3.2.P.8.3-17. Stability Data for Drug Product Emergency Supply Lot EK1768 Stored at -70 °C (-90 to -60 °C)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles[a]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[b]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	(b)	(b) (4)	(b) (4)				
1W	WOFS	Meets (b)		NS	(b) (4)			
2W	WOFS	Meets (b)		NS				
1M	WOFS	Meets (b)		NS				
3M	WOFS	Meets (b)		NS				
6M	WOFS	Meets (b)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[b]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1W							NS	NS	NS
2W							NS	NS	NS
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Subvisible particles are reported per container.
b. Acceptance criteria in place at time of testing.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, MCR = Meets Compendial Requirements, WOFS = White to off-white suspension

Table 3.2.P.8.3-18. Stability Data for Drug Product Emergency Supply Lot EJ1686 Stored at -70 °C (-90 to -60 °C)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles[a]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[b]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0[c]	WOFS	(b)	(b) (4)	(b) (4)				
1W	WOFS	Meets (b)		NS	(b) (4)			
2W	WOFS	Meets (b)		NS				
1M	WOFS	Meets (b)		NS				
3M	WOFS	Meets (b)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[b]	(b) (4)								
0[c]	(b) (4)						(b) (4)		Pass
1W							NS	NS	NS
2W							NS	NS	NS
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Subvisible particles are reported per container.
b. Acceptance criteria in place at time of testing.
c. Initial data (t0) are not from release testing, with the exception of sterility and endotoxin. Analysis for t0 were repeated for this study.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, MCR = Meets Compendial Requirements, WOFS = White to off-white suspension

Table 3.2.P.8.3-19. Stability Data for Drug Product Emergency Supply Lot EJ1685 Stored at -70 °C (-90 to -60 °C)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles[a]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[b]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	White to off-white suspension	(b)	(b) (4)	(b) (4)				
1W	WOFS	(b)		NS	(b) (4)			
2W	WOFS	Meets	(b)	NS				
1M	WOFS	Meets	(b)	NS				
3M	WOFS	Meets	(b)	NS				
6M	WOFS	Meets	(b)	(b) (4)				
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[b]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1W									NS
2W							NS	NS	NS
1M							NS	NS	NS
3M							NS	NS	NS
6M							NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Subvisible particles are reported per container.
b. Acceptance criteria in place at time of testing.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-20. Stability Data for Drug Product Emergency Supply Lot EJ0553 Stored at -70 °C (-90 to -60 °C)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles[a]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[b]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	White to off-white suspension	(b)	(b) (4)	(b) (4)				
1M	WOFS	(b)		NS	(b) (4)			
3M	WOFS	Meets (b)		(b) (4)				
6M	WOFS	Meets (b)						
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[b]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M									NS
3M							(b) (4)	NS	Pass
6M								NS	Pass
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Subvisible particles are reported per container.
b. Acceptance criteria in place at time of testing.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-21. Stability Data for Drug Product Emergency Supply Lot EE8493 Stored at -70 °C (-90 to -60 °C)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles[a]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	WOFS	(b)	(b) (4)	(b) (4)				
1M	WOFS	(b)		NS	(b) (4)			
3M	WOFS	Meets (b)		(b) (4)				
6M	WOFS	Meets (b)						
9M	WOFS	Meets (b)		NS	(b) (4)			
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1M							NS	NS	NS
3M							(b) (4)	NS	Pass
6M								NS	Pass
9M							NS	NS	NS
12M							S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; WOFS = White to off-white suspension, (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-22. Stability Data for Drug Product Emergency Supply Lot EE8492 Stored at -70 °C (-90 to -60 °C)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles[b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	(b)	(b) (4)	(b) (4)				
1W	WOFS	(b)		NS	(b) (4)			
2W	WOFS	(b)		NS				
1M	WOFS	(b)		NS				
2M	WOFS	(b)		NS				
3M	WOFS	Meets (b)		(b) (4)				
6M	WOFS	Meets (b)						
9M	WOFS	Meets (b)		NS	(b) (4)			
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			Container Closure Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
1W							NS	NS	NS
2W							NS	NS	NS
1M							NS	NS	NS
2M							NS	NS	NS
3M							(b) (4)	NS	Pass
6M								NS	Pass
9M							NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; WOFS = White to off-white suspension, (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-23. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40820-P Stored at -70 ± 10 °C

Time (Months)	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	White to off-white suspension/Free from observable particles	7.4 ± 0.5	(b) (4)					
0	Pass	(b) (4)	(b) (4)					
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
6	Pass	(b) (4)	(b) (4)					

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria[a]	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	(b) (4)	Sterile
0	(b) (4)					Pass
1						NS
3						NS
6						Pass

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

Table 3.2.P.8.3-24. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-P Stored at -70 ± 10 °C

Time (Months)	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	**White to off-white suspension/Free from observable particles**	**7.4 ± 0.5**	(b) (4)					
0	Pass	(b) (4)	(b) (4)					
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
6	Pass	(b) (4)	(b) (4)					

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	(b) (4)	**Sterile**
0	(b) (4)					Pass
1						NS
3						NS
6						Pass

a. Accepta

S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle

Table 3.2.P.8.3-25. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-C Stored at -70 ± 10 °C

Time (Months)	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	**White to off-white suspension, free from observable particles**	**7.4 ± 0.5**	(b) (4)					
0	Pass	(b) (4)	(b) (4)					
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
6	Pass	(b) (4)	(b) (4)					

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	(b) (4)	**Sterile**
0	(b) (4)					Pass
1						NS
3						NS
6						Pass

a. Accep

S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle

Table 3.2.P.8.3-26. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-A Stored at -70 ± 10 °C

Time (Months)	Appearance	pH	Subvisible Particles	LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	**White to off-white suspension/Free from observable particles**	**7.4 ± 0.5**	(b) (4)				
0	Pass	(b) (4)	(b) (4)				
1	Pass	NS	NS	NS	(b) (4)		
3	Pass	NS	NS	NS			
6	Pass	(b) (4)	(b) (4)				

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	(b) (4)	**Sterile**
0	(b) (4)					Pass
1						NS
3						NS
6						Pass

a. Accepta

S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle

Table 3.2.P.8.3-27. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40620-E Stored at -70 ± 10 °C

Time (Months)	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	**White to off-white suspension/Free from observable particles**	**7.4 ± 0.5**	(b) (4)					
0	Pass	(b) (4)	(b) (4)					
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
6	Pass	(b) (4)	(b) (4)					

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	(b) (4)	**Sterile**
0	(b) (4)					Pass
1						NS
3						NS
6						Pass

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

Table 3.2.P.8.3-28. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40620-A Stored at -70 ± 10 °C

Time (Months)	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	**White to off-white suspension/Free from observable particles**	**7.4 ± 0.5**	(b) (4)					
0	Pass	(b) (4)	(b) (4)					
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
6	Pass	(b) (4)	(b) (4)					

Time (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	(b) (4)	**Sterile**
0	(b) (4)					Pass
1						NS
3						NS
6						Pass

a. Accep

S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle

Table 3.2.P.8.3-29. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40420-A Stored at -70 ± 10 °C

Analytical Procedure/Quality Attribute	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	**White to off-white suspension/Free from observable particles**	**7.4 ± 0.5**	(b) (4)					
0	Pass	(b) (4)	(b) (4)					
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
4	Pass	NS	NS	NS				
6	Pass	NS	NS	NS				
9	Pass	NS	NS	NS				
12	Pass	(b) (4)	(b) (4)					
18	S	NS	NS	NS	S	S	S	S
24	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Timepoint/ Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	**Report Results (mg/mL)**	(b) (4)	**Sterile**
0	(b) (4)					Pass
1						NS
3						NS
4						NS
6						NS
9						NS
12						NS
18	S	S	S	S	S	NS
24	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Method integration parameters were changed after the 1 month time point
S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, RP = Result Pending

Table 3.2.P.8.3-30. Stability Data for Polymun Scientific Drug Product BNT162b2 Non-clinical Lot CoVVAC/270320 Stored at -70 ± 10 °C

Time	Appearance	LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria[a]	Report Results (Visual Appearance and Visible Particles)	Report Results (nm)	Report Results	Report Results (%)	Report Results (mg/mL)
0	Pass	(b) (4)			
2W	Pass				
1M	Pass				
2M	Pass				
3M	Pass				
6M	Pass				

Time	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (%)
0	(b) (4)	(b) (4)			
2W					
1M					
2M					
3M					
6M					

a. Acceptance criteria in place at time of te

W = Week, M = Month, S = Scheduled, LNP = Lipid Nanoparticle

Inverted Vial Stability Studies

Table 3.2.P.8.3-31. Stability Data for Drug Product Lot EL7834 Stored at -90 to -60 °C (Inverted Vials)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
6M	WOFS	Meets						
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Container closure integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
6M							NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
Abbreviations: M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOFS = White to off-white suspension, (b) (4), NGD = No Growth Detected

Table 3.2.P.8.3-32. Stability Data for Drug Product Lot EK4242 Stored at -90 to -60 °C (Inverted Vials)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
6M	WOFS	Meets						
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Container closure integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
6M							NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
Abbreviations: M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOFS = White to off-white suspension, (b) (4), NGD = No Growth Detected

Table 3.2.P.8.3-33. Stability Data for Drug Product Lot EL1491 Stored at -90 to -60 °C (Inverted Vials)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	**White to off-white suspension**	**May contain white to off-white opaque, amorphous particles**	**7.4 ± 0.5**	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
6M	WOFS	Meets						
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Container closure integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
6M									NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
Abbreviations: M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOFS = White to off-white suspension, (b) (4) NGD = No Growth Detected

Table 3.2.P.8.3-34. Stability Data for Drug Product Lot EL3249 Stored at -90 to -60 °C (Inverted Vials)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
6M	WOFS	Meets						
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Container closure integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
6M							NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
Abbreviations: M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOFS = White to off-white suspension, (b) (4), NGD = No Growth Detected

Table 3.2.P.8.3-35. Stability Data for Drug Product Lot EL3248 Stored at -90 to -60 °C (Inverted Vials)

Analytical Procedure/Quality Attribute	Appearance		pH	Subvisible Particles [b]	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)				
0	WOFS	Meets	(b) (4)	(b) (4)				
6M	WOFS	Meets						
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis	Endotoxin (LAL)	Sterility	Container closure integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity			
Timepoint/ Acceptance Criteria[a]	(b) (4)								
0	(b) (4)						(b) (4)		Pass
6M							NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
Abbreviations: M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOFS = White to off-white suspension, (b) (4), NGD = No Growth Detected

Figure 3.2.P.8.3-1. LNP Polydispersity Results for Emergency Supply and PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-2. LNP Size Results for Emergency Supply and PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-3. RNA Content Results for Emergency Supply and PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-4. RNA Encapsulation Results for Emergency Supply and PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-5. Lipid Content (ALC-0315) Results for Emergency Supply & PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-6. Lipid Content (ALC-0159) Results for Emergency Supply & PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-7. Lipid Content (DSPC) Results for Emergency Supply & PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-8. Lipid Content (Cholesterol) Results for Emergency Supply & PPQ Drug Product Lots Stored -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-9. RNA Integrity Results for Emergency Supply and PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)

Figure 3.2.P.8.3-10. IVE Results for Emergency Supply and PPQ Drug Product Lots Stored at -90 to -60 °C

(b) (4)