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STABILITY DATA – ACCELERATED

Data from stability studies on BNT162b2 drug product lots stored at the accelerated conditions of -60 to -30 °C (setpoint -40 °C), -40 ± 5 °C, -20 ± 5 °C and/or 5 ± 3 °C are presented for emergency supply and process performance qualification lots manufactured by multiple manufacturing sites.

All studies are listed in Table 3.2.P.8.3-1. Available data is shown in through Table 3.2.P.8.3-71 and in Figure 3.2.P.8.3-1 through Figure 3.2.P.8.3-28.

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

Lot Number	DP Lot Use	Stability Study Start	Stability Data Presented	Data Table Location
(BNT162b2)				
EN6199 (Pfizer, Kalamazoo, Line (b))	Stability, Emergency Supply[b] Process performance qualification	February 2021	-60 to -30 °C: Release	Table 3.2.P.8.3-2
			-20 °C: 3 months	Table 3.2.P.8.3-10
			5 °C: 3 months	Table 3.2.P.8.3-31
EL3249 (Pfizer Kalamazoo, Line (b))	Stability, Emergency Supply[b], Process performance qualification	December 2020	-20 °C upright vials: 6 months	Table 3.2.P.8.3-11
			-20 °C inverted vials: 6 months	Table 3.2.P.8.3-66
			5 °C upright vials: 6 months	Table 3.2.P.8.3-32
			5 °C inverted vials: 6 months	Table 3.2.P.8.3-71
EL9267 (Pfizer, Kalamazoo, Line ( )	Stability, Clinical, Commercial, Process performance qualification	January 2021	-60 to -30 °C: Release	Table 3.2.P.8.3-3
			-20 °C: 3 months	Table 3.2.P.8.3-12
			5 °C: 3 month	Table 3.2.P.8.3-33
EL3248 (Pfizer, Kalamazoo, Line ( )	Stability, Emergency Supply[b], Process performance qualification	December 2020	-20 °C upright vials: 6 months	Table 3.2.P.8.3-13
			-20 °C inverted vials: 6 months	Table 3.2.P.8.3-65
			5 °C upright vials: 6 months	Table 3.2.P.8.3-34
			5 °C inverted vials: 6 months	Table 3.2.P.8.3-70
EM4965 (Polymun Scientific/Pfizer, Puurs)	Stability, Clinical, Commercial, Process performance qualification	February 2021	-60 to -30 °C: Release	Table 3.2.P.8.3-4
			-20 °C: 3 months	Table 3.2.P.8.3-14
			5 °C: 3 months	Table 3.2.P.8.3-35
EL7834 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply[b], Process performance qualification	December 2020	-20 °C upright vials: 6 months	Table 3.2.P.8.3-15
			-20 °C inverted vials: 6 months	Table 3.2.P.8.3-62
			5 °C upright vials: 6 months	Table 3.2.P.8.3-36
			5 °C inverted vials: 6 months	Table 3.2.P.8.3-67
EN1195 (mibe/Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	March 2021	-20 °C: 3 months	Table 3.2.P.8.3-16
			5 °C: 3 months	Table 3.2.P.8.3-37
EK4242 (mibe/Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	December 2020	-20 °C upright vials: 6 months	Table 3.2.P.8.3-17
			-20 °C inverted vials: 6 months	Table 3.2.P.8.3-63
			5 °C upright vials: 6 months	Table 3.2.P.8.3-38
			5 °C inverted vials: 6 months	Table 3.2.P.8.3-68
EP2166 (Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	January 2021	-20 °C: 3 months	Table 3.2.P.8.3-18
			5 °C: 3 months	Table 3.2.P.8.3-39

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

Lot Number	DP Lot Use	Stability Study Start	Stability Data Presented	Data Table Location
EL8713 (Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	January 2021	-20 °C: 3 months	Table 3.2.P.8.3-19
			5 °C: 3 months	Table 3.2.P.8.3-40
EM6950 (Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	January 2021	-60 to -30 °C: Release	Table 3.2.P.8.3-5
			-20 °C: 3 months	Table 3.2.P.8.3-20
			5 °C: 3 months	Table 3.2.P.8.3-41
EL8723 (Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	January 2021	-60 to -30 °C: Release	Table 3.2.P.8.3-6
			-20 °C: 3 months	Table 3.2.P.8.3-21
			5 °C: 3 months	Table 3.2.P.8.3-42
EL1491 (Pfizer, Puurs)	Stability, Emergency Supply[b], Process performance qualification	December 2020	-20 °C upright vials: 6 months	Table 3.2.P.8.3-22
			-20 °C inverted vials: 6 months	Table 3.2.P.8.3-64
			5 °C upright vials: 6 months	Table 3.2.P.8.3-43
			5 °C inverted vials: 6 months	Table 3.2.P.8.3-69
EH9899 (Pfizer, Kalamazoo)	Stability, Emergency Supply[b]	November 2020	-20 °C: 6 months	Table 3.2.P.8.3-23
			5 °C: 3 months (complete)	Table 3.2.P.8.3-44
EJ1688 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[b], Clinical inventory	November 2020	-20 °C: 6 months (complete)	Table 3.2.P.8.3-24
			5 °C: 3 months (complete)	Table 3.2.P.8.3-45
EK1768 (Polymun Scientific/Pfizer, Puurs	Stability, Emergency Supply[b], Clinical inventory	November 2020	-20 °C: 6 months (complete)	Table 3.2.P.8.3-25
			5 °C: 3 months (complete)	Table 3.2.P.8.3-46
EJ1686 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[b], Clinical inventory	November 2020	-20 °C: 6 months (complete)	Table 3.2.P.8.3-26
			5 °C: 3 months (complete)	Table 3.2.P.8.3-47
EJ1685 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[b], Clinical inventory	November 2020	-60 to -30 °C: 6 months	Table 3.2.P.8.3-7
			-20 °C: 6 months (complete)	Table 3.2.P.8.3-27
			5 °C: 3 months (complete)	Table 3.2.P.8.3-48
EJ0553 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[b], Clinical inventory	November 2020	-60 to -30 °C: 6 months (complete)	Table 3.2.P.8.3-8
			-20 °C: 6 months (complete)	Table 3.2.P.8.3-28
			5 °C: 3 months (complete)	Table 3.2.P.8.3-49
EE8493 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[b], Clinical inventory	September 2020	-60 to -30 °C: 6 months (complete)	Table 3.2.P.8.3-9
			-20 °C: 6 months (complete)	Table 3.2.P.8.3-29
			5 °C: 3 months (complete)	Table 3.2.P.8.3-50
EE8492 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply[b]	September 2020	-20 °C: 6 months (complete)	Table 3.2.P.8.3-30
			5 °C: 3 months (complete)	Table 3.2.P.8.3-51
EE3813[c] (Polymun Scientific/Pfizer, Puurs)	Stability, clinical	August 2020	5 °C: 3 months (complete)	Table 3.2.P.8.3-52

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

Lot Number	DP Lot Use	Stability Study Start	Stability Data Presented	Data Table Location
ED3938[d] (Polymun Scientific/Pfizer, Puurs)	Stability, clinical inventory	August 2020	5 °C: 3 months (complete)	Table 3.2.P.8.3-53
BCV40720-C (Polymun Scientific)	Stability, clinical	August 2020	5 °C: 3 months (complete)	Table 3.2.P.8.3-54
BCV40720-A (Polymun Scientific)	Stability, clinical	August 2020	5 °C: 3 months (complete)	Table 3.2.P.8.3-55
BCV40620-E (Polymun Scientific)	Stability, clinical	July 2020	5 °C: 3 months (complete)	Table 3.2.P.8.3-56
BCV40620-A (Polymun Scientific)	Stability, Clinical	July 2020	5 °C: 3 months (complete)	Table 3.2.P.8.3-57
BCV40420-A (Polymun Scientific)	Stability, Clinical	May 2020	-40 °C: 12 months	Table 3.2.P.8.3-58
			5 °C: 6 months (complete)	Table 3.2.P.8.3-59
CoVVAC/270320 (Polymun Scientific)	Stability, non-clinical toxicology	March 2020[a]	-40 °C: 3 months	Table 3.2.P.8.3-60
			5 °C: 6 months (complete)	Table 3.2.P.8.3-61

a. -40 °C study started in April 2020.
b. Emergency supply designation applies to US market.
c. This lot number is equivalent to BCV40820-P.
d. This lot number is equivalent to BCV40720-P.
TBD = To Be Determined

Table 3.2.P.8.3-2. Stability Data for PPQ Drug Product EN6199 Stored at -60 to -30 °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)				
6M	S	S	S	S	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
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
6M	S	S	S	S	S	S
12M	S	S	S	S	S	S
18M	S	S	S	S	S	S
24M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-3. Stability Data for PPQ Drug Product EL9267 Stored at -60 to -30 °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	(b) (Meets)	(b) (4)	(b) (4)				
6M	S	S	S	S	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
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria [a]	(b) (4)					
0	(b) (4)					
6M	S	S	S	S	S	S
12M	S	S	S	S	S	S
18M	S	S	S	S	S	S
24M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-4. Stability Data for PPQ Drug Product EM4965 Stored at -60 to -30 °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))	(b) (4)	(b) (4)				
6M	S	S	S	S	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
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
6M	S	S	S	S	S	S
12M	S	S	S	S	S	S
18M	S	S	S	S	S	S
24M	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, (b) (4) , LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-5. Stability Data for PPQ Drug Product EM6950 Stored at -60 to -30 °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)				
6M	S	S	S	S	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
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
6M	S	S	S	S	S	S
12M	S	S	S	S	S	S
18M	S	S	S	S	S	S
24M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-6. Stability Data for PPQ Drug Product EL8723 Stored at -60 to -30 °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)				
6M	S	S	S	S	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
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0[c]	(b) (4)					
6M	S	S	S	S	S	S
12M	S	S	S	S	S	S
18M	S	S	S	S	S	S
24M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension.

Table 3.2.P.8.3-7. Stability Data for Drug Product Emergency Supply Batch EJ1685 Stored at -60 to -30 °C

Analytical Procedure/ Quality Attribute	Appearance		pH	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)			
1M	WOFS	Meets (b) (4)					
3M	WOFS	Meets (b) (4)					
6M	WOFS	Meets (b) (4)					

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-8. Stability Data for Drug Product Emergency Supply Batch EJ0553 Stored at -60 to -30 °C

Analytical Procedure/ Quality Attribute	Appearance		pH	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)			
1M	WOFS	(b)					
3M	WOFS	Meets (b)					
6M	WOFS	Meets (b)					

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

a. Acceptance crite
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-9. Stability Data for Drug Product Emergency Supply Lot EE8493 Stored at -60 to -30 °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)				
1M	WOFS	(b)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. Original result investigated and invalidated. No result reported as next time point was available for testing at the time the 1 month investigation concluded.
W = Week, M = Month, S = To be Scheduled NS = Not Scheduled at Time Point, (b) (4), LNP = Lipid Nanoparticle, MCR = Meets Compendial Requirements, WOFS = White to off-white suspension

Table 3.2.P.8.3-10. Stability Data for PPQ Drug Product EN6199 Stored at -20 ± 5 °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	(b) (Meets)	(b) (4)	(b) (4)	(b) (4)			
2W	WOFS	(b) (Meets)		NS				
1M	WOFS	(b) (Meets)		NS				
2M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-11. Stability Data for PPQ Drug Product EL3249 Upright Vials Stored at -20 ± 5 °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	(b) (Meets)	(b) (4)	(b) (4)	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	WOFS	(b) (Meets)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-12. Stability Data for PPQ Drug Product EL9267 Stored at -20 ± 5 °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	(b) (Meets)	(b) (4)	(b) (4)				
2W	WOFS	(b) (Meets)		NS	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
2M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle

Table 3.2.P.8.3-13. Stability Data for Drug Product EL3248 Upright Vials Stored at -20 ± 5 °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	(b) (4) (Meets)	(b) (4)	(b) (4)				
1M	WOFS	(b) (4) (Meets)		NS	(b) (4)			
3M	WOFS	(b) (4) (Meets)		NS				
6M	WOFS	(b) (4) (Meets)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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

Table 3.2.P.8.3-14. Stability Data for PPQ Drug Product EM4965 Stored at -20 ± 5 °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	(b) (Meets)	(b) (4)	b) (4)				
2W	WOFS	(b) (Meets)		NS	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
2M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-15. Stability Data for PPQ Drug Product EL7834 Upright Vials Stored at -20 ± 5 °C (Polymun/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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

Table 3.2.P.8.3-16. Stability Data for PPQ Drug Product EN1195 Stored at -20 ± 5 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0[c]	(b) (4)					
1M						
2M						
3M						
6M	S	S	S	S	S	S

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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-17. Stability Data for PPQ Drug Product EK4242 Upright Vials Stored at -20 ± 5 °C (mibe/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-18. Stability Data for PPQ Drug Product EP2166 Stored at -20 ± 5 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-19. Stability Data for PPQ Drug Product EL8713 Stored at -20 ± 5 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-20. Stability Data for PPQ Drug Product EM6950 Stored at -20 ± 5 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-21. Stability Data for PPQ Drug Product EL8723 Stored at -20 ± 5 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-22. Stability Data for PPQ Drug Product EL1491 Upright Vials Stored at -20 ± 5 °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)				
1M	WOFS	Meets			(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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

Table 3.2.P.8.3-23. Stability Data for Drug Product Emergency Supply Lot EH9899 Stored at -20 ± 5 °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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
2M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0[c]	(b) (4)					
1M						
2M						
3M						
6M						

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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-24. Stability Data for Drug Product Emergency Supply Lot EJ1688 Stored at -20 ± 5 °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)				
1M	WOFS	Meets (b) (4)		NS	(b) (4)			
2M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
2M						
3M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector

Table 3.2.P.8.3-25. Stability Data for Drug Product Emergency Supply Lot EK1768 Stored at -20 ± 5 °C

Analytical Procedure/ Quality Attribute	Appearance		pH	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) (4)	(b) (4)	(b) (4)			
1M	WOFS	Meets					
3M	WOFS	Meets					
6M	WOFS	Meets					

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-26. Stability Data for Drug Product Emergency Supply Lot EJ1686 Stored at -20 ± 5 °C

Analytical Procedure/ Quality Attribute	Appearance		pH	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[b]	WOFS	(b)	(b) (4)	(b) (4)			
1M	WOFS	Meets (b) (4)					
3M	WOFS	Meets (b) (4)					
6M	WOFS	Meets (b) (4)					

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0[b]	(b) (4)					
1M						
3M						
6M						

a. Acceptance criteria in place at time of testing.
b. T=0 testing performed for the lot (release values not utilized).
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-27. Stability Data for Drug Product Emergency Supply Lot EJ1685 Stored at -20 ± 5 °C

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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-28. Stability Data for Drug Product Emergency Supply Lot EJ0553 Stored at -20 ± 5 °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)				
1M	WOFS	(b)		NS	(b) (4)			
3M	WOFS	(b)		NS				
6M	WOFS	(b)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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; (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.8.3-29. Stability Data for Drug Product Emergency Supply Lot EE8493 Stored at -20 ± 5 °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)				
1M	WOFS	(b)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. Original result investigated and invalidated with no result being reported.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, (b) (4), LNP = Lipid Nanoparticle, MCR = Meets Compendial Requirements, WOFS = White to off-white suspension

Table 3.2.P.8.3-30. Stability Data for Drug Product Emergency Supply Lot EE8492 Stored at -20 ± 5 °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	(b)		NS				
2M	WOFS	(b)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	WOFS	Meets (b) (4)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1W						
2W						
1M						
2M						
3M						
6M						

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. Original result investigated and invalidated. No result reported as next time point was available for testing at the time the 1 month investigation concluded.
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, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-31. Stability Data for PPQ Drug Product EN6199 Stored at 2-8 °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	(b) (Meets)	(b) (4)	(b) (4)				
2W	WOFS	(b) (Meets)		NS	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
2M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-32. Stability Data for PPQ Drug Product EL3249 Upright Vials Stored at 2-8 °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	(b) (Meets)	(b) (4)	(b) (4)				
1M	WOFS	(b) (Meets)		NS	(b) (4)			
3M	WOFS	(b) (Meets)		NS				
6M	WOFS	(b) (Meets)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-33. Stability Data for PPQ Drug Product EL9267 Stored at 2-8 °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	(b) (Meets)	(b) (4)	(b) (4)				
2W	WOFS	(b) (Meets)		NS	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
2M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle

Table 3.2.P.8.3-34. Stability Data for PPQ Drug Product EL3248 Upright Vials Stored at 2-8 °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	(b) (Meets)	(b) (4)	(b) (4)				
1M	WOFS	(b) (Meets)		NS	(b) (4)			
3M	WOFS	(b) (Meets)		NS				
6M	WOFS	(b) (Meets)		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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, (b) (4), LNP = Lipid Nanoparticle

Table 3.2.P.8.3-35. Stability Data for PPQ Drug Product EM4965 Stored at 2-8 °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	(b) (Meets)	(b) (4)	(b) (4)				
2W	WOFS	(b) (Meets)		NS	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
2M	WOFS	(b) (Meets)		NS				
3M	WOFS	(b) (Meets)		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-36. Stability Data for PPQ Drug Product EL7834 Upright Vials Stored at 2 to 8 °C (Polymun/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	(b) (Meets)		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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; (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-37. Stability Data for PPQ Drug Product EN1195 Stored at 2-8 °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)			
3M	WOFS	Meets		NS				
6M	S	S	S	S	S	S	S	S

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0[c]	(b) (4)					
1M						
3M						
6M	S	S	S	S	S	S

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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-38. Stability Data for PPQ Drug Product EK4242 Upright Vials Stored at 2 to 8 °C (mibe/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-39. Stability Data for PPQ Drug Product EP2166 Stored at 2-8 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-40. Stability Data for PPQ Drug Product EL8713 Stored at 2-8 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-41. Stability Data for PPQ Drug Product EM6950 Stored at 2-8 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-42. Stability Data for PPQ Drug Product EL8723 Stored at 2-8 °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

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
2W						
1M						
2M						
3M						
6M	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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-43. Stability Data for PPQ Drug Product EL1491 Upright Vials Stored at 2-8 °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)				
1M	WOFS	Meets		NS	(b) (4)			
3M	WOFS	Meets		NS				
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/ Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint/ Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
3M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; WOFS = White to off-white suspension

Table 3.2.P.8.3-44. Stability Data for Drug Product Emergency Supply Lot EH9899 Stored at 2-8 °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	Meets	(b) (4)	(b) (4)				
1W	WOFS	Meets		NS	(b) (4)			
2W	WOFS	Meets		NS				
1M	WOFS	Meets		NS				
3M	WOFS	Meets		NS				

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

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, (b) (4), LNP = Lipid Nanoparticle, WOFS = White to off-white suspension

Table 3.2.P.8.3-45. Stability Data for Drug Product Emergency Supply Lot EJ1688 Stored at 2 to 8 °C

Analytical Procedure/Quality Attribute	Appearance		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint / Acceptance Criteriaa	**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)					
2W	WOFS	(b)					
1M	WOFS	Meets (b) (4)					
3M	WOFS	Meets (b) (4)					

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

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); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-46. Stability Data for Drug Product Emergency Supply Lot EK1768 Stored at 2-8 °C

Analytical Procedure/Quality Attribute	Appearance		pH	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	Meets (b) (4)					
2W	WOFS	Meets (b) (4)					
1M	WOFS	Meets (b) (4)					
3M	WOFS	Meets (b) (4)					

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

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) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-47. Stability Data for Drug Product Emergency Supply Lot EJ1686 Stored at 2-8 °C

Analytical Procedure/Quality Attribute	Appearance		pH	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[b]	WOFS	(b)	(b) (4)	(b) (4)			
1W	WOFS	Meets (b) (4)					
2W	WOFS	Meets (b) (4)					
1M	WOFS	Meets (b) (4)					
3M	WOFS	Meets (b) (4)					

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

a. Acceptance criteria in place at time of testing.
b. T=0 testing performed for this lot (release values not utilitzed).
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-48. Stability Data for Drug Product Emergency Supply Lot EJ1685 Stored at 2-8 °C

Analytical Procedure/Quality Attribute	Appearance		pH	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)					
2W	WOFS	Meets (b) (4)					
1M	WOFS	Meets (b) (4)					
3M	WOFS	Meets (b) (4)					

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

a. Acceptance criteria i (b) (4)

Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-49. Stability Data for Drug Product Emergency Supply Lot EJ0553 Stored at 2-8 °C

Analytical Procedure/Quality Attribute	Appearance		pH	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)			
1M	WOFS	(b)					
3M	WOFS	Meets (b) (4)					

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

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) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-50. Stability Data for Drug Product Emergency Supply Lot EE8493 Stored at 2-8 °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)				
1M	WOFS	(b)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		NS				

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

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. Original result investigated and invalidated. No result reported as next time point was available for testing at the time the 1 month investigation concluded.
W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, (b) (4), LNP = Lipid Nanoparticle, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-51. Stability Data for Drug Product Emergency Supply Lot EE8492 Stored at 2-8 °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)	(b) (4)			
1W	WOFS	(b)		NS				
2W	WOFS	(b)		NS				
1M	WOFS	(b)		NS				
2M	WOFS	(b)		NS				
3M	WOFS	Meets (b) (4)		S				

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

a. Acceptance criteria in place at time of testing.
b. Subvisible particles are reported per container.
c. Original result investigated and invalidated. No result reported as next time point was available for testing at the time the 1 month investigation concluded.
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, MCR = Meets Compendial Requirements

Table 3.2.P.8.3-52. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40820-P Stored at 2-8 °C

Time (Month)	Appearance	pH	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					
2	Pass					
3	Pass					

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					

a. Accepta

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

Table 3.2.P.8.3-53. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-P Stored at 2-8 °C

Time (Month)	Appearance	pH	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				
2	Pass	NS				
3	Pass	(b) (4)				

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					

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

Table 3.2.P.8.3-54. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-C Stored at 2-8 °C

Time (Month)	Appearance	pH	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				
2	Pass	NS				
3	Pass	(b) (4)				

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					

a. Accepta

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

Table 3.2.P.8.3-55. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-A Stored at 2-8 °C

Time (Month)	Appearance	pH	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				
2	Pass	NS				
3	Pass	(b) (4)				

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					

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

Table 3.2.P.8.3-56. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40620-E Stored at 2-8 °C

Time (Month)	Appearance	pH	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				
2	Pass	NS				
3	Pass	(b) (4)				

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					

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

Table 3.2.P.8.3-57. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40620-A Stored at 2-8 °C

Time (Month)	Appearance	pH	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				
2	Pass	NS				
3	Pass	(b) (4)				

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					

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

Table 3.2.P.8.3-58. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40420-A Stored at -40 ± 5 °C

Analytical Procedure/ Quality Attribute	Appearance	Sub-Visible Particles		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
					LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Timepoint/ Acceptance Criteria[a]	White to off-white suspension/Free from observable particles	(b) (4)		7.4 ± 0.5	(b) (4)			
0	Pass	(b) (4)		(b) (4)	(b) (4)			
1	Pass	NS	NS	NS				
2	Pass	NS	NS	NS				
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	HPLC-CAD				Capillary Gel Electrophoresis	Sterility
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	
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
2						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.
S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, RP = Result Pending

Table 3.2.P.8.3-59. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40420-A Stored at 2-8 °C

Time (Month)	Appearance	pH	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				
2	Pass	NS				
3	Pass	NS				
4	Pass	NS				
6	Pass	(b) (4)				

Time (Month)	HPLC-CAD				Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity
Acceptance Criteria[a]	**Report Results (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	**Report Result (mg/mL)**	(b) (4)
0	(b) (4)				
1					
2					
3					
4					
6					

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

Table 3.2.P.8.3-60. Stability Data for Polymun Scientific Drug Product BNT162b2 Non-clinical Lot CoVVAC/270320 Stored at -40 ± 5 °C

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

Time (Month)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Bioburden
Acceptance Criteria[a]	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	(b) (4)	
0	(b) (4)					(b) (4)
1						NS
2						NS
3						NS
6	S	S	S	S	S	NS
9	S	S	S	S	S	NS
12	S	S	S	S	S	NS
18	S	S	S	S	S	NS
24	S	S	S	S	S	S

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

Table 3.2.P.8.3-61. Stability Data for Polymun Scientific Drug Product BNT162b2 Non-clinical Lot CoVVAC/270320 Stored at 2-8 °C

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

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

Inverted Vial Stability Studies

Table 3.2.P.8.3-62. Stability Data for PPQ Drug Product EL7834 Inverted Vials Stored at -20 ± 5 °C (Polymun/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-63. Stability Data for PPQ Drug Product EK4242 Inverted Vials Stored at -20 ± 5 °C (mibe/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-64. Stability Data for PPQ Drug Product EL1491 Inverted Vials Stored at -20 ± 5 °C (Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)	(b) (4)			
6M	WOFS	Meets						

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-65. Stability Data for PPQ Drug Product EL3248 Inverted Vials Stored at -20 ± 5 °C (Pfizer, Kalamazoo)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-66. Stability Data for PPQ Drug Product EL3249 Inverted Vials Stored at -20 ± 5 °C (Pfizer, Kalamazoo)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-67. Stability Data for PPQ Drug Product EL7834 Inverted Vials Stored at 2 to 8 °C (PolymunPfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets	(b) (4)	NS	(b) (4)			
6M	WOFS	Meets	(b) (4)	(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-68. Stability Data for PPQ Drug Product EK4242 Inverted Vials Stored at 2 to 8 °C (mibe/Pfizer, Puurs)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-69. Stability Data for PPQ Drug Product EL1491 Inverted Vials Stored at 2 to 8 °C (Pfizer, Puurs)

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	Meets (b) (4)	(b) (4)	(b) (4)				
6M	WOFS	Meets (b) (4)						

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-70. Stability Data for PPQ Drug Product EL3248 Inverted Vials Stored at 2 to 8 °C (Pfizer, Kalamazoo)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Table 3.2.P.8.3-71. Stability Data for PPQ Drug Product EL3249 Inverted Vials Stored at 2 to 8 °C (Pfizer, Kalamazoo)

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	Meets	(b) (4)	(b) (4)				
1M	WOFS	Meets		NS	(b) (4)			
6M	WOFS	Meets		(b) (4)				

Analytical Procedure/Quality Attribute	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity
Timepoint / Acceptance Criteria[a]	(b) (4)					
0	(b) (4)					
1M						
6M						

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; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

Figure 3.2.P.8.3-1. LNP Polydispersity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-2. LNP Polydispersity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-3. LNP Size Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-4. LNP Size Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-5. RNA Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-6. RNA Encapsulation Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-7. RNA Encapsulation Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-8. ALC-0315 Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-9. ALC-0159 Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Condition

(b) (4)

Figure 3.2.P.8.3-10. DSPC Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-11. Cholesterol Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-12. RNA Integrity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

Figure 3.2.P.8.3-13. RNA Integrity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-14. IVE Results for Emergency Supply and PPQ Drug Product Lots at Accelerated -20 ± 5 °C Conditions

(b) (4)

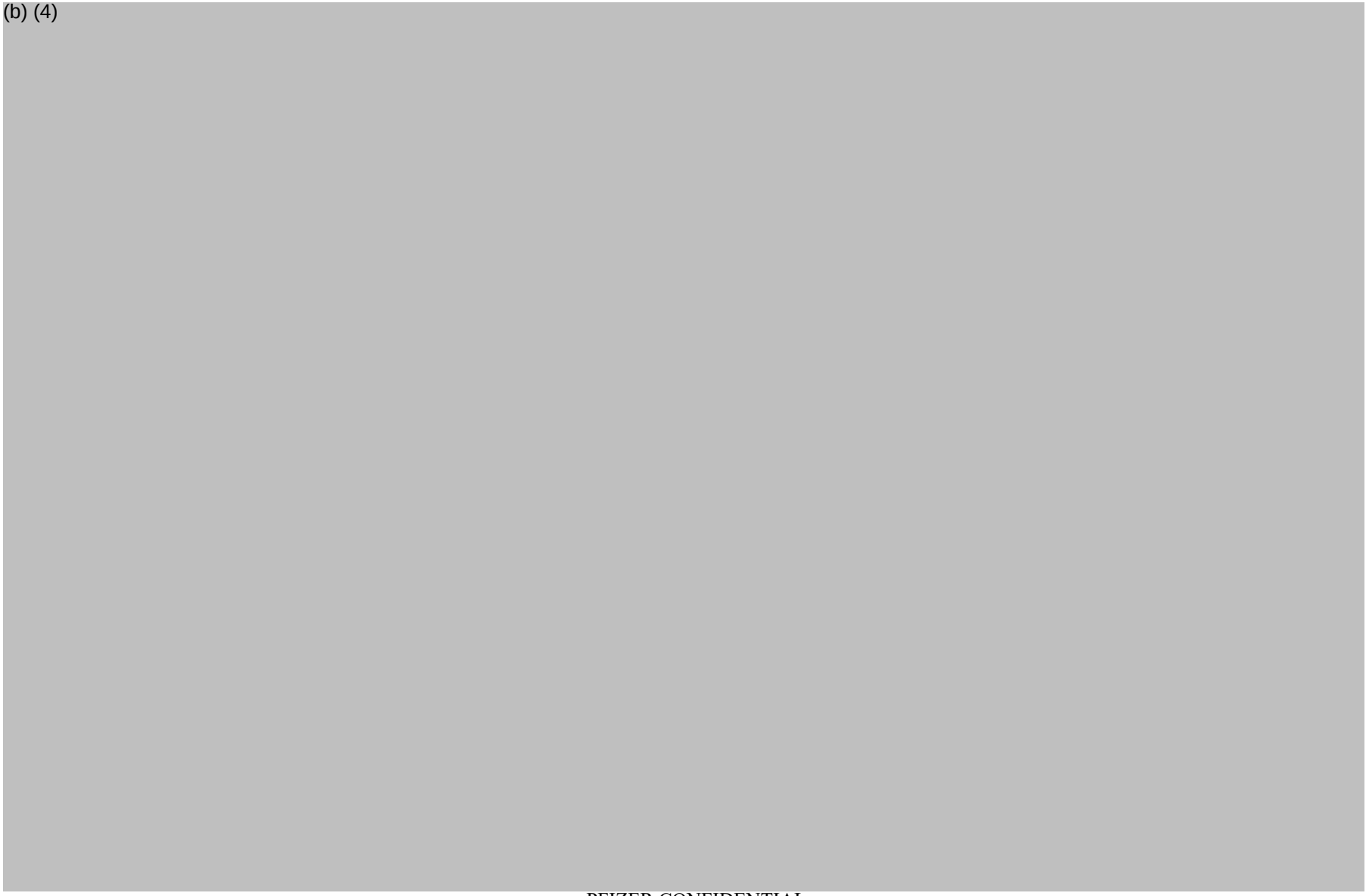

Figure 3.2.P.8.3-15. LNP Polydispersity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-16. LNP Polydispersity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-17. LNP Size Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-18. LNP Size Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-19. RNA Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-20. RNA Encapsulation Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-21. RNA Encapsulation Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions Expanded View

(b) (4)

Figure 3.2.P.8.3-22. ALC-0315 Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-23. ALC-0159 Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-24. DSPC Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-25. Cholesterol Lipid Content Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-26. RNA Integrity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)

Figure 3.2.P.8.3-27. RNA Integrity Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions Expanded View

Figure 3.2.P.8.3-28. IVE Results for Emergency Supply and PPQ Drug Product Lots at Accelerated 2 to 8 °C Conditions

(b) (4)