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3.2.P.8.3. 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), -20 ± 5 °C and/or 5 ± 3 °C are presented for emergency supply and process performance qualification lots manufactured by Pfizer, Kalamazoo, mibe (with fill and finish at Pfizer Puurs), Polymun (with fill and finish at Pfizer, Puurs) and Pfizer, Puurs.

All studies are listed in [Table 3.2.P.8.3-1](#). Available data is shown in [Table 3.2.P.8.3-2](#) through [Table 3.2.P.8.3-61](#).

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: 1 month	Table 3.2.P.8.3-10
			5 °C: 1 month	Table 3.2.P.8.3-31
EL3249 (Pfizer, Kalamazoo, Line (b))	Stability, Emergency Supply ^b , Process performance qualification	December 2020	-20 °C: 3 months	Table 3.2.P.8.3-11
			5 °C: 3 months	Table 3.2.P.8.3-32
EL9267 (Pfizer, Kalamazoo, Line (l) b)	Stability, Clinical, Commercial, Process performance qualification	January 2021	-60 to -30 °C: Release	Table 3.2.P.8.3-3
			-20 °C: 1 month	Table 3.2.P.8.3-12
			5 °C: 1 month	Table 3.2.P.8.3-33
EL3248 (Pfizer, Kalamazoo, Line (l) b)	Stability, Emergency Supply ^b , Process performance qualification	December 2020	-20 °C: 3 months	Table 3.2.P.8.3-13
			5 °C: 3 months	Table 3.2.P.8.3-34
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: 1 month	Table 3.2.P.8.3-14
			5 °C: 1 month	Table 3.2.P.8.3-35
EL7834 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^b , Process performance qualification	December 2020	-20 °C: 3 months	Table 3.2.P.8.3-15
			5 °C: 3 months	Table 3.2.P.8.3-36
EN1195 (mibe/Pfizer, Puurs)	Stability, Emergency Supply ^b , Process performance qualification	March 2021	-20 °C: 1 month	Table 3.2.P.8.3-16
			5 °C: 1 month	Table 3.2.P.8.3-37
EK4242 (mibe/Pfizer, Puurs)	Stability, Emergency Supply ^b , Process performance qualification	December 2020	-20 °C: 3 months	Table 3.2.P.8.3-17
			5 °C: 3 months	Table 3.2.P.8.3-38
EP2166 (Pfizer, Puurs)	Stability, Emergency Supply ^b , Process performance qualification	January 2021	-20 °C: 2 months	Table 3.2.P.8.3-18
			5 °C: 2 months	Table 3.2.P.8.3-39
EL8713 (Pfizer, Puurs)	Stability, Emergency Supply ^b , Process performance qualification	January 2021	-20 °C: 2 months	Table 3.2.P.8.3-19
			5 °C: 2 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: 2 months	Table 3.2.P.8.3-20
			5 °C: 2 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: 2 months	Table 3.2.P.8.3-21
			5 °C: 2 months	Table 3.2.P.8.3-42
EL1491 (Pfizer, Puurs)	Stability, Emergency Supply ^b , Process performance qualification	December 2020	-20 °C: 3 months	Table 3.2.P.8.3-22
			5 °C: 3 months	Table 3.2.P.8.3-43
		November 2020	-20 °C: 3 months	Table 3.2.P.8.3-23

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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
EH9899 (Pfizer, Kalamazoo)	Stability, Emergency Supply ^b		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: 3 months	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: 3 months	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: 3 months	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: 3 months	Table 3.2.P.8.3-7
			-20 °C: 3 months	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: 3 months	Table 3.2.P.8.3-8
			-20 °C: 3 months	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	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
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

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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
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: 9 months	Table 3.2.P.8.3-58
			5 °C: 6 months (complete)	Table 3.2.P.8.3-59
CoVAC/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 Drug Product EN6199 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	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

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Table 3.2.P.8.3-3. Stability Data for Drug Product EL9267 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) (Meets)	(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

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Table 3.2.P.8.3-4. Stability Data for Drug Product EM4965 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	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

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Table 3.2.P.8.3-5. Stability Data for Drug Product EM6950 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	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

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Table 3.2.P.8.3-6. Stability Data for Drug Product EL8723 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 ^c	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 ^c	Pending	Pending	Pending	Pending	(b) (4)	Pending
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.

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.

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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) (4)	(b) (4)	(b) (4)			
1M	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
3M	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
6M	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)					
1M	(b) (4)					
3M	Pending	Pending	Pending	Pending	(b) (4)	
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point.
 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

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

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point.
 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

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Table 3.2.P.8.3-9. Stability Data for Drug Product 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) (4)	(b) (4)	(b) (4)				
1M	WOFS	(b) (4)		(b) (4)	NS	(b) (4)		
3M	WOFS	Meets (b) (4)		(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)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
0	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
1M	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
3M	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
6M	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

a. Acceptance criteria in place at time of testing. Current specification applied at the 6 month time point.
 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

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Table 3.2.P.8.3-10. Stability Data for Drug Product EN6199 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) (Meets)	(b) (4)	(b) (4)				
2W	WOFS	(b) (Meets)	(b) (4)	NS				
1M	WOFS	(b) (Meets)		NS				
2M	S	S	S	NS	S	S	S	S
3M	S	S	S	NS	S	S	S	S
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	(b) (4)					
1M	(b) (4)					
2M	S	S	S	S	S	S
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-11. Stability Data for Drug Product EL3249 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) (Meets)	(b) (4)	(b) (4)				
1M	WOFS	(b) (Meets)			NS	(b) (4)		
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)					
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.

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

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Table 3.2.P.8.3-12. Stability Data for Drug Product EL9267 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) (Meets)	(b) (4)	(b) (4)				
2W	WOFS	(b) (Meets)	(b) (4)	NS				
1M	WOFS	(b) (Meets)	(b) (4)	NS	(b) (4)			
2M	S	S	S	NS	S	S	S	S
3M	S	S	S	NS	S	S	S	S
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	(b) (4)					
1M	(b) (4)					
2M	S	S	S	S	S	S
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-13. Stability Data for Drug Product EL3248 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) (Meets)	(b) (4)	(b) (4)					
1M	WOFS	(b) (Meets)		NS					(b) (4)
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)					
1M						
3M						
6M						

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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Table 3.2.P.8.3-14. Stability Data for Drug Product EM4965 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) (Meets)	(b) (4)	(b) (4)					
2W	WOFS	(b) (Meets)		NS					(b) (4)
1M	WOFS	(b) (Meets)		NS					
2M	S	S	S	NS	S	S	S	S	
3M	S	S	S	NS	S	S	S	S	
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						
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-15. Stability Data for Drug Product EL7834 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	Meets (b) (4)	(b) (4)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		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)					
1M						
3M						
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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Table 3.2.P.8.3-16. Stability Data for Drug Product EN1195 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	Pending	Pending	Pending	NS	Pending	Pending	(b) (4)	
2M	S	S	S	NS	S	S	S	S
3M	S	S	S	NS	S	S	S	S
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	Pending	Pending	Pending	Pending	(b) (4)	
2M	S	S	S	S	S	S
3M	S	S	S	S	S	S
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).

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

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Table 3.2.P.8.3-17. Stability Data for Drug Product EK4242 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	Meets (b) (4)	(b) (4)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		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)					
1M	(b) (4)					
3M	(b) (4)					
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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Table 3.2.P.8.3-18. Stability Data for Drug Product EP2166 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	Meets	(b) (4)	(b) (4)							
2W	WOFS	Meets (b) (4)		NS					(b) (4)		
1M	WOFS	Meets (b) (4)		NS							
2M	Pending	Pending		NS					(b) (4)	Pending	Pending
3M	S	S	S	NS					S	S	S
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	(b) (4)					
1M	(b) (4)					
2M	(b) (4)				Pending	(b) (4)
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-19. Stability Data for Drug Product EL8713 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	Meets (b) (4)	(b) (4)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS (b) (4)				
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	S	S	S	NS	S	S	S	S
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	(b) (4)					
1M	(b) (4)					
2M	(b) (4)					
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-20. Stability Data for Drug Product EM6950 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	Meets (b) (4)	(b) (4)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS (b) (4)				
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	S	S	S	NS	S	S	S	S
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	(b) (4)					
1M	(b) (4)					
2M	(b) (4)				Pending	Pending
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-21. Stability Data for Drug Product EL8723 Stored at $-20 \pm 5 \text{ }^\circ\text{C}$

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)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS	(b) (4)			
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	S	S	S	NS	S	S	S	S
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
Acceptance Criteria ^a	(b) (4)					
0	(b) (4)					
2W						
1M						
2M	(b) (4)				Pending	(b) (4)
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-22. Stability Data for Drug Product EL1491 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	Meets (b) (4)	(b) (4)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		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)	(b) (4)	(b) (4)	(b) (4)		
0	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
1M	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
3M	(b) (4)	(b) (4)	(b) (4)	(b) (4)	Pending	(b) (4)
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point..

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

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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)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	S	S	S	S	S	S	S	S

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. Current specifications applied at the 3 month time point.

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

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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) (4)	(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	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)					
1M						
2M						
3M						
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point.

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

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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 (b) (4)	(b) (4)	(b) (4)			
3M	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
6M	S	S	S	S	S	S	S

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

a. Acceptance criteria in place at time of testing. Current effective acceptance criteria established at the 3 month time point.
 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

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

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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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) (4)	7.4 ± 0.5	(b) (4)			
0	WOFS	(b) (4)	(b) (4)	(b) (4)			
1M	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
3M	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
6M	S	S	S	S	S	S	S

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

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point.
 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

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

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point.

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

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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) (4)	(b) (4)					
1M	WOFS	(b) (4)	(b) (4)	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)	(b) (4)	(b) (4)	(b) (4)		
0	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
1M	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
3M	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
6M	(b) (4)	(b) (4)	(b) (4)	(b) (4)	Pending	(b) (4)

a. Acceptance criteria in place at time of testing. Current version of specification effective at 6 month time point

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

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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) (4)	(b) (4)	(b) (4)				
1W	WOFS	(b) (4)		NS	(b) (4)			
2W	WOFS	(b) (4)		NS				
1M	WOFS	(b) (4)		NS				
2M	WOFS	(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)	(b) (4)	(b) (4)	(b) (4)		
0	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
1W	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
2W	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
1M	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
2M	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
3M	(b) (4)	(b) (4)	(b) (4)	(b) (4)		
6M	(b) (4)	(b) (4)	(b) (4)	(b) (4)	Pending	(b) (4)

a. Acceptance criteria in place at time of testing. Current version of specification effective at 6 month time point.
 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

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

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Table 3.2.P.8.3-32. Stability Data for Drug Product EL3249 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 Criteriaa	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	(b) (4)	(b) (4)			
0	WOFS	(b) (Meets)	(b) (4)	(b) (4)				
1M	WOFS	(b) (Meets)	(b) (4)	NS	(b) (4)		(b) (4)	
3M	WOFS	(b) (Meets)		NS	Pending	Pending		
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 Criteriaa	(b) (4)					
0	(b) (4)					
1M	(b) (4)					
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

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Table 3.2.P.8.3-33. Stability Data for Drug Product EL9267 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) (Meets)	(b) (4)					
2W	WOFS	(b) (Meets)	(b) (4)	NS	(b) (4)			
1M	WOFS	(b) (Meets)		NS				
2M	S	S	S	NS	S	S	S	S
3M	S	S	S	NS	S	S	S	S
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	(b) (4)					
1M	Pending	Pending	Pending	Pending	(b) (4)	
2M	S	S	S	S	S	S
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-34. Stability Data for Drug Product EL3248 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) (4) (Meets)	(b) (4)					
1M	WOFS	(b) (4) (Meets)	(b) (4)	NS	(b) (4)			
3M	WOFS	(b) (4) (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)					
1M	(b) (4)					
3M	(b) (4)					Pending
6M	S	S	S	S	S	(b) (4)

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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

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Table 3.2.P.8.3-36. Stability Data for Drug Product EL7834 Stored at 2 to 8 °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	Meets (b) (4)	(b) (4)					
1M	WOFS	Meets (b) (4)	(b) (4)	NS	(b) (4)			
3M	WOFS	Meets (b) (4)		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)				(b) (4)	(b) (4)
1M						
3M					Pending	
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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Table 3.2.P.8.3-37. Stability Data for Drug Product EN1195 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 ^c	WOFS	Meets (b) (4)	(b) (4)					
1M	Pending	Pending	Pending	NS	Pending	Pending	(b) (4)	
3M	S	S	S	NS	S	S	S	S
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)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
0 ^c	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
1M	Pending	Pending	Pending	Pending	(b) (4)	(b) (4)
3M	S	S	S	S	S	S
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).

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

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Table 3.2.P.8.3-38. Stability Data for Drug Product EK4242 Stored at 2 to 8 °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	Meets (b) (4)	(b) (4)					
1M	WOFS	Meets (b) (4)	(b) (4)	NS	(b) (4)			
3M	WOFS	Meets (b) (4)		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)				(b) (4)	(b) (4)
1M						
3M					Pending	
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.

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

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Table 3.2.P.8.3-39. Stability Data for Drug Product EP2166 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)					
2W	WOFS	Meets (b) (4)	(b) (4)		(b) (4)			(b) (4)
1M	WOFS	Meets (b) (4)			NS			
2M	Pending	Pending			NS			Pending
3M	S	S	S		NS	S	S	S
6M	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	(b) (4)					
1M	(b) (4)					
2M	Pending	Pending	Pending	Pending	Pending	(b) (4)
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-40. Stability Data for Drug Product EL8713 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)	(b) (4)					
2W	WOFS	Meets (b) (4)		NS					(b) (4)
1M	WOFS	Meets (b) (4)		NS					
2M	WOFS	Meets (b) (4)		NS					
3M	S	S	S	NS	S	S	S	S	
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	S	S	S	S	S	S
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

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Table 3.2.P.8.3-41. Stability Data for Drug Product EM6950 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)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS				
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	S	S	S	NS	S	S	S	S
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	(b) (4)					
1M	(b) (4)					
2M	(b) (4)					
3M	S	S	S	S	S	S
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

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Table 3.2.P.8.3-42. Stability Data for Drug Product EL8723 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)	(b) (4)				
2W	WOFS	Meets (b) (4)		NS	(b) (4)			
1M	WOFS	Meets (b) (4)		NS				
2M	WOFS	Meets (b) (4)		NS				
3M	S	S	S	NS	S	S	S	S
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	S	S	S	S	S	S
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

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Table 3.2.P.8.3-43. Stability Data for Drug Product EL1491 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)	(b) (4)				
1M	WOFS	Meets (b) (4)		NS	(b) (4)			
3M	WOFS	Meets (b) (4)		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)				(b) (4)	(b) (4)
1M	(b) (4)					
3M	(b) (4)				Pending	
6M	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point..

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

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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	RNA	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)					
1W	WOFS	Meets (b) (4)		NS					(b) (4)
2W	WOFS	Meets (b) (4)		NS					
1M	WOFS	Meets (b) (4)		NS					
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)					
1W						
2W						
1M						
3M						

a. Acceptance criterion

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

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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 Criteria	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)				
1W	WOFS	(b) (4)					
2W	WOFS	(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	(b) (4)					
0	(b) (4)					
1W						
2W						
1M						
3M						

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 months time point.

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

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

LNP = Lipid Nanoparticle; HPLC-CAD

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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) (4)	(b) (4)	(b) (4)			
1W	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
2W	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
1M	WOFS	Meets (b) (4)	(b) (4)	(b) (4)			
3M	WOFS	Meets (b) (4)	(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	(b) (4)					
2W	(b) (4)					
1M	(b) (4)					
3M	(b) (4)					

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point.
 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

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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) (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. Current specifications implemented at the 3 month time point.

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

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

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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) (4)	(b) (4)				
1W	WOFS	(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. Current specifications implemented at the 3 month time point.

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

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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) (4)	(b) (4)				
1M	WOFS	(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)					
1M						
3M						

a. Acceptance criteria in place at time of testing. Current specifications implemented at the 3 month time point. 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

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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) (4)	(b) (4)	(b) (4)				
1M	WOFS	(b) (4)			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. Current specification applied at the 3 month time point.
 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

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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) (4)	(b) (4)	(b) (4)				
1W	WOFS	(b) (4)	(b) (4)	NS				
2W	WOFS	(b) (4)	(b) (4)	NS				
1M	WOFS	(b) (4)	(b) (4)	NS				
2M	WOFS	(b) (4)	(b) (4)	NS				
3M	WOFS	Meets (b) (4)	(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	(b) (4)					
2W	(b) (4)					
1M	(b) (4)					
2M	(b) (4)					
3M	(b) (4)					

- a. Acceptance criteria in place at time of testing. Current specification applied at the 3 month time point.
 - 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

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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)	(b) (4)	(b) (4)	(b) (4)
0	Pass	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
1	Pass	NS	(b) (4)	(b) (4)	(b) (4)	(b) (4)
2	Pass	NS	(b) (4)	(b) (4)	(b) (4)	(b) (4)
3	Pass	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(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)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
1	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
2	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
3	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

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

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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

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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					
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

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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

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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

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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)	(b) (4)	(b) (4)	(b) (4)
0	Pass	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
1	Pass	NS	(b) (4)	(b) (4)	(b) (4)	(b) (4)
2	Pass	NS	(b) (4)	(b) (4)	(b) (4)	(b) (4)
3	Pass	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(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)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
1	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
2	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
3	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

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

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

Time (Month)	Appearance	Sub-Visible Particles		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
					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)			
1	Pass	NS	NS	NS	(b) (4)			
2	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS	(b) (4)			
4	Pass	NS	NS	NS	(b) (4)			
6	Pass	NS	NS	NS	(b) (4)			
9	Pass	NS	NS	NS	(b) (4)			
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)	HPLC-CAD				Capillary Gel Electrophoresis	Sterility
	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)	(b) (4)	Sterile
0	(b) (4)					Pass
1	(b) (4)					NS
2	(b) (4)					NS
3	(b) (4)					NS
4	(b) (4)					NS
6	(b) (4)					NS
9	(b) (4)					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

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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

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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)	(b) (4)		
0	Pass	(b) (4)						
1	Pass	NS	NS	NS	(b) (4)			
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

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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

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