

TABLE OF CONTENTS

LIST OF TABLES.....1
3.2.P.8.3. STABILITY DATA - LONG TERM.....3

LIST OF TABLES

Table 3.2.P.8.3-1. Summary Table of Drug Product Long Term Stability Studies4
Table 3.2.P.8.3-2. Stability Data for Drug Product EN6199 Stored at -90 to -60 °C6
Table 3.2.P.8.3-3. Stability Data for Drug Product EL3249 Stored at -90 to -60 °C.....7
Table 3.2.P.8.3-4. Stability Data for Drug Product EL9267 Stored at -90 to -60 °C.....8
Table 3.2.P.8.3-5. Stability Data for Drug Product EL3248 Stored at -90 to -60 °C.....10
Table 3.2.P.8.3-6. Stability Data for Drug Product EM4965 Stored at -90 to -60 °C.....11
Table 3.2.P.8.3-7. Stability Data for Drug Product EL7834 Stored at -90 to -60 °C.....13
Table 3.2.P.8.3-8. Stability Data for Drug Product EN1195 Stored at -90 to -60 °C14
Table 3.2.P.8.3-9. Stability Data for Drug Product EK4242 Stored at -90 to -60 °C15
Table 3.2.P.8.3-10. Stability Data for Drug Product EP2166 Stored at -90 to -60 °C.....16
Table 3.2.P.8.3-11. Stability Data for Drug Product EL8713 Stored at -90 to -60 °C.....18
Table 3.2.P.8.3-12. Stability Data for Drug Product EM6950 Stored at -90 to -60 °C.....20
Table 3.2.P.8.3-13. Stability Data for Drug Product EL8723 Stored at -90 to -60 °C.....22
Table 3.2.P.8.3-14. Stability Data for Drug Product EL1491 Stored at -90 to -60 °C.....24
Table 3.2.P.8.3-15. Stability Data for Drug Product Emergency Supply Lot EH9899
Stored at -90 to -60 °C.....25
Table 3.2.P.8.3-16. Stability Data for Drug Product Emergency Supply Lot EJ1688
Stored at -90 to -60 °C.....27
Table 3.2.P.8.3-17. Stability Data for Drug Product Emergency Supply Lot EK1768
Stored at -70 °C (-90 to -60 °C).....28
Table 3.2.P.8.3-18. Stability Data for Drug Product Emergency Supply Lot EJ1686
Stored at -70 °C (-90 to -60 °C).....29
Table 3.2.P.8.3-19. Stability Data for Drug Product Emergency Supply Lot EJ1685
Stored at -70 °C (-90 to -60 °C).....31
Table 3.2.P.8.3-20. Stability Data for Drug Product Emergency Supply Lot EJ0553
Stored at -70 °C (-90 to -60 °C).....32
Table 3.2.P.8.3-21. Stability Data for Drug Product Emergency Supply Lot EE8493
Stored at -70 °C (-90 to -60 °C).....33

Table 3.2.P.8.3-22. Stability Data for Drug Product Emergency Supply Lot EE8492 Stored at -70 °C (-90 to -60 °C).....	34
Table 3.2.P.8.3-23. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40820-P Stored at -70 ± 10 °C	35
Table 3.2.P.8.3-24. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-P Stored at -70 ± 10 °C	36
Table 3.2.P.8.3-25. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-C Stored at -70 ± 10 °C	37
Table 3.2.P.8.3-26. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40720-A Stored at -70 ± 10 °C.....	38
Table 3.2.P.8.3-27. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40620-E Stored at -70 ± 10 °C	39
Table 3.2.P.8.3-28. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40620-A Stored at -70 ± 10 °C.....	40
Table 3.2.P.8.3-29. Stability Data for Polymun Scientific Drug Product BNT162b2 Lot BCV40420-A Stored at -70 ± 10 °C.....	41
Table 3.2.P.8.3-30. Stability Data for Polymun Scientific Drug Product BNT162b2 Non-clinical Lot CoVVAC/270320 Stored at -70 ± 10 °C.....	42

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3.2.P.8.3. STABILITY DATA - LONG TERM

Data from stability studies on BNT162b2 drug product lots stored at the long term condition of -90 to -60 °C are presented for emergency supply lots and process performance qualification lots manufactured by Polymun Scientific (with fill and finish at Pfizer, Puurs), mibe (with fill and finish at Pfizer, Puurs), Pfizer, Puurs and Pfizer, Kalamazoo (b) (4) ().

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

All studies are listed in [Table 3.2.P.8.3-1](#). Results are provided in Table 3.2.P.8.3-2 through Table 3.2.P.8.3-30. All results, generated to date, met the acceptance criteria at the time of testing.

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

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Table Location
(BNT162b2)				
EN6199 (Pfizer, Kalamazoo, Line (b))	Stability, Emergency Supply ^a , Process performance qualification	February 2021	-90 to -60 °C: 1 month	Table 3.2.P.8.3-2
EL3249 (Pfizer, Kalamazoo, Line (b))	Stability, Clinical, Emergency Supply ^a , Process performance qualification	December 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-3
EL9267 (Pfizer, Kalamazoo, Line () b	Stability, Emergency Supply ^a , Process performance qualification	January 2021	-90 to -60 °C: 1 month	Table 3.2.P.8.3-4
EL3248 (Pfizer, Kalamazoo, Line () b	Stability, Clinical, Emergency Supply ^a , Process performance qualification	December 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-5
EM4965 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	February 2021	-90 to -60 °C: 1 month	Table 3.2.P.8.3-6
EL7834 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	December 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-7
EN1195 (mibe/Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	March 2021	-90 to -60 °C: 1 month	Table 3.2.P.8.3-8
EK4242 (mibe/Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	December 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-9
EP2166 (Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	January 2021	-90 to -60 °C: 2 months	Table 3.2.P.8.3-10
EL8713 (Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	January 2021	-90 to -60 °C: 2 months	Table 3.2.P.8.3-11
EM6950 (Pfizer, Puurs)	Stability, Emergency Supply ^a , Process performance qualification	January 2021	-90 to -60 °C: 2 months	Table 3.2.P.8.3-12
EL8723 (Pfizer, Puurs)	Stability, Clinical, Emergency Supply ^a , Process performance qualification	January 2021	-90 to -60 °C: 2 months	Table 3.2.P.8.3-13
EL1491 (Pfizer, Puurs)	Stability, Emergency Supply ^a , Clinical, Process performance qualification	December 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-14

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

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Table Location
EH9899 (Pfizer, Kalamazoo)	Stability, Emergency Supply ^a	November 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-15
EJ1688 (mibe/Pfizer, Puurs)	Stability, Emergency Supply ^a	November 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-16
EK1768 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Clinical inventory	November 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-17
EJ1686 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Clinical inventory	November 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-18
EJ1685 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Clinical inventory	November 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-19
EJ0553 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Clinical inventory	November 2020	-90 to -60 °C: 3 months	Table 3.2.P.8.3-20
EE8493 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a , Clinical inventory	September 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-21
EE8492 (Polymun Scientific/Pfizer, Puurs)	Stability, Emergency Supply ^a	September 2020	-90 to -60 °C: 6 months	Table 3.2.P.8.3-22
EE3813 ^c (Polymun Scientific/Pfizer, Puurs)	Stability, clinical	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-23
ED3938 ^d (Polymun Scientific/Pfizer, Puurs)	Stability, clinical inventory	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-24
BCV40720-C (Polymun Scientific)	Stability, clinical	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-25
BCV40720-A (Polymun Scientific)	Stability, clinical	August 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-26
BCV40620-E (Polymun Scientific)	Stability, clinical	July 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-27
BCV40620-A (Polymun Scientific)	Stability, clinical	July 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-28
BCV40420-A (Polymun Scientific)	Stability, clinical	May 2020	-70 ± 10 °C: 9 months	Table 3.2.P.8.3-29
CoVAC/270320 (Polymun Scientific)	Stability, non-clinical toxicology	March 2020	-70 ± 10 °C: 6 months (Complete)	Table 3.2.P.8.3-30

a. Emergency supply designation applies to US market.

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

c. This lot number is equivalent to BCV40820-P

d. This lot number is equivalent to BCV40720-P.

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Table 3.2.P.8.3-2. Stability Data for Drug Product EN6199 Stored at -90 to -60 °C

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

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

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

, NGD = No growth detected

Table 3.2.P.8.3-3. Stability Data for Drug Product EL3249 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

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

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Table 3.2.P.8.3-4. Stability Data for Drug Product EL9267 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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)	(b) (4)	NS	(b) (4)			
1M	WOFS	Meets (b) (4)		NS				
2M	S	S		S	NS	S	S	S
3M	S	S	S	NS	S	S	S	S
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

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Table 3.2.P.8.3-4. Stability Data for Drug Product EL9267 Stored at -90 to -60 °C

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

[REDACTED]

Table 3.2.P.8.3-5. Stability Data for Drug Product EL3248 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

a. Acceptance criteria in place at time of testing. 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, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

, No growth detected

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Table 3.2.P.8.3-6. Stability Data for Drug Product EM4965 Stored at -90 to -60 °C

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

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

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Table 3.2.P.8.3-6. Stability Data for Drug Product EM4965 Stored at -90 to -60 °C

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-7. Stability Data for Drug Product EL7834 Stored at -90 to -60 °C

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

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

a. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.
 b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, WOS = White to off-white suspension, (b) (4), LNP = Lipid Nanoparticle

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Table 3.2.P.8.3-8. Stability Data for Drug Product EN1195 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Time	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity	Endotoxin (LAL)	Sterility	Dye Incursion Container Closure Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content					
Acceptance Criteria ^a	(b) (4)								
0	(b) (4)								Pending
1M	Pending	Pending	Pending	Pending	(b) (4)		NS	NS	NS
2M	S	S	S	S	S	S	NS	NS	NS
3M	S	S	S	S	S	S	NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.
- c. 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, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

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Table 3.2.P.8.3-9. Stability Data for Drug Product EK4242 Stored at -90 to -60 °C

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

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

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

b. Subvisible particles are reported per container.

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

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Table 3.2.P.8.3-10. Stability Data for Drug Product EP2166 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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)	(b) (4)	NS	(b) (4)		(b) (4)	
1M	WOFS	Meets (b) (4)		NS				
2M	Pending	Pending		NS			Pending	Pending
3M	S	S		S	NS	S	S	S
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

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Table 3.2.P.8.3-10. Stability Data for Drug Product EP2166 Stored at -90 to -60 °C

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-11. Stability Data for Drug Product EL8713 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

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Table 3.2.P.8.3-11. Stability Data for Drug Product EL8713 Stored at -90 to -60 °C

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-12. Stability Data for Drug Product EM6950 Stored at -90 to -60 °C

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

Time	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity	Endotoxin (LAL)	Sterility	Dye Incursion Container Closure Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content					
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)	Pass
2W	(b) (4)				(b) (4)	(b) (4)	(b) (4)	(b) (4)	NS
1M	(b) (4)				(b) (4)	(b) (4)	(b) (4)	(b) (4)	NS
2M	(b) (4)				(b) (4)	(b) (4)	(b) (4)	(b) (4)	NS
3M	S	S	S	S	S	S	NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

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Table 3.2.P.8.3-12. Stability Data for Drug Product EM6950 Stored at -90 to -60 °C

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

Table 3.2.P.8.3-13. Stability Data for Drug Product EL8723 Stored at -90 to -60 °C

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

Table 3.2.P.8.3-13. Stability Data for Drug Product EL8723 Stored at -90 to -60 °C

- a. Acceptance criteria in place at time of testing.
- b. Subvisible particles are reported per container.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

Table 3.2.P.8.3-14. Stability Data for Drug Product EL1491 Stored at -90 to -60 °C

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Time	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content					Container Closure Integrity
Acceptance Criteria ^a	(b) (4)								
0	(b) (4)				(b) (4)		(b) (4)		Pass
1M	(b) (4)						NS	NS	NS
3M	(b) (4)				Pending	70	NS	NS	NS
6M	S	S	S	S	S	S	NS	NS	NS
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing. 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, LNP = Lipid Nanoparticle; WOFS = White to off-white suspension, (b) (4)

090177e19703f72bApproved On: 12-May-2021 12:39 (GMT)

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

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

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

090177e19703f72bApprovedApproved On: 12-May-2021 12:39 (GMT)

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

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

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

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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	Meets (b) (4)		NS				
3M	WOFS	Meets (b) (4)		NS				
6M	S	S	S	S	S	S	S	S
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

a. Acceptance criteria in place at time of testing. 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, WOFS = White to off-white suspension, (b) (4) ,

LNP = Lipid Nanoparticle, NGD = No Growth Detected

090177e19703f72bApprovedApproved On: 12-May-2021 12:39 (GMT)

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

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

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

a. Subvisible particles are reported per container.

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

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, MCR = Meets Compendial Requirements, WOFS = White to off-white suspension

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

- a. Subvisible particles are reported per container.
 - b. Acceptance criteria in place at time of testing. Current specifications applied at the 3 month time point.
 - c. Initial data (t0) are not from release testing, with the exception of sterility and endotoxin. Analysis for t0 were repeated for this study.
- W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4); LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, MCR = Meets Compendial Requirements, WOFS = White to off-white suspension

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

a. Subvisible particles are reported per container.

b. Acceptance criteria in place at time of testing. Current specifications applied at the 3 months time point.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

090177e19703f72bApprovedApproved On: 12-May-2021 12:39 (GMT)

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

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

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

a. Subvisible particles are reported per container.

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

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point; NMT = No more than; (b) (4) ; LNP = Lipid Nanoparticle; HPLC-CAD = high performance liquid chromatography-charged aerosol detector, WOFS = White to off-white suspension

090177e19703f72bApprovedApproved On: 12-May-2021 12:39 (GMT)

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

Time	Appearance		pH	Subvisible Particles ^a	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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)		(b) (4)				
6M	WOFS	Meets (b) (4)						
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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

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

b. Subvisible particles are reported per container.

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

Time	Appearance		pH	Subvisible Particles ^b	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visual)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
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)		(b) (4)				
6M	WOFS	Meets (b) (4)						
9M	S	S	S	NS	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Time	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity	Endotoxin	Sterility	Dye Incursion Container Closure Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content					
Acceptance Criteria ^b	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	Pass
0	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	Pass
1W								NS	NS
2W								NS	NS
1M								NS	NS
2M								NS	NS
3M								NS	Pass
6M					Pending		Pending	NS	Pass
9M	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	NS	NS	NS
24M	S	S	S	S	S	S	S	S	S

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

b. Subvisible particles are reported per container

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

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

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

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

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)

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

Time (Months)	Appearance	pH	Subvisible Particles		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^a	White to off-white suspension/Free from observable particles	7.4 ± 0.5	(b) (4)					
0	Pass	(b) (4)						
1	Pass	NS	NS	NS	(b) (4)			
3	Pass	NS	NS	NS				
4	Pass	NS	NS	NS				
6	Pass	NS	NS	NS				
9	Pass	NS	NS	NS				
12	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 (Months)	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	RNA Integrity	Sterility
Acceptance Criteria ^a	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	Report Results (mg/mL)	(b) (4)	Sterile
0	(b) (4)					Pass
1						NS
3						NS
4						NS
6						NS
9						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.
 - b. Method integration parameters were changed after the 1 month time point
- S = Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle

090177e19703f72bApprovedApproved On: 12-May-2021 12:39 (GMT)

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

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

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

a. Acceptance criteria in place at time of testing.
 W = Week, M = Month, S = Scheduled, LNP = Lipid Nanoparticle

090177e19703f72b\Approved\Approved On: 12-May-2021 12:39 (GMT)