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3.2.P.8.3. STABILITY DATA – ADDITIONAL STORAGE CONDITIONS – TRIS/SUCROSE DRUG PRODUCT

Data from stability studies on drug product lots stored at the additional storage conditions of $-50 \pm 5^\circ\text{C}$, $-20 \pm 5^\circ\text{C}$ and $5 \pm 3^\circ\text{C}$ are presented in this section. A list of the studies and available data are provided in Table 3.2.P.8.3-1. Results are discussed in [Section 3.2.P.8.1 Stability Summary and Conclusions – Tris-Sucrose](#).

Table 3.2.P.8.3-1. Summary of Tris/Sucrose Drug Product Stability Studies for Additional Storage Conditions

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Data Table Location
EX0490 (single dose)	Primary Stability	March 2021	-50°C : 1 month (Complete)	Table 3.2.P.8.3-2
			-20°C : 6 months (Complete)	Table 3.2.P.8.3-5
			5°C : 6 months (Complete)	Table 3.2.P.8.3-25
EW4564 (multi-dose)	Primary Stability	April 2021	-50°C : 1 month (Complete)	Table 3.2.P.8.3-3
			-20°C : 6 months (Complete)	Table 3.2.P.8.3-6
			5°C : 6 months (Complete)	Table 3.2.P.8.3-26
EW4565 (multi-dose)	Primary Stability	April 2021	-50°C : 1 month (Complete)	Table 3.2.P.8.3-4
			-20°C : 6 months (Complete)	Table 3.2.P.8.3-7
			5°C : 6 months (Complete)	Table 3.2.P.8.3-27
FC8273 (multi-dose)	Process Performance Qualification, Puurs FC1 2.25 mL Fill, 30 µg dose. Supportive Stability	June 2021	-20°C : 3 months (Complete)	Table 3.2.P.8.3-8
			5°C : 6 months ^b	Table 3.2.P.8.3-28
FE4394 (multi-dose)	Process Performance Qualification, Puurs FC2 2.25 mL Fill, 30 µg dose. Supportive Stability	July 2021	-20°C : 1 month (Complete) ^a	Table 3.2.P.8.3-9
			5°C : 6 months ^b	Table 3.2.P.8.3-29
FJ5683 ^c (multi-dose)	Process Performance Qualification, Puurs FC1 2.25 mL Fill, 30 µg dose. Supportive Stability	Sep 2021	-20°C : 1 month (Complete) ^a	Table 3.2.P.8.3-10
			5°C : 3 months ^b	Table 3.2.P.8.3-30
FK5127 (multi-dose)	Process Performance Qualification, Puurs WSL10 1.3 mL fill, 10 µg dose. Supportive Stability	Sep 2021	-20°C : 1 month (Complete) ^a	Table 3.2.P.8.3-11
			5°C : 3 months ^b	Table 3.2.P.8.3-31
FK5128 (multi-dose)	Process Performance Qualification, Puurs WSL10 0.4 mL fill, 3 µg dose. Supportive Stability	Sep 2021	-20°C : 1 month (Complete) ^a	Table 3.2.P.8.3-12
			5°C : 3 months ^b	Table 3.2.P.8.3-32

Table 3.2.P.8.3-1. Summary of Tris/Sucrose Drug Product Stability Studies for Additional Storage Conditions

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Data Table Location
FK5618 (multi-dose)	Process Performance Qualification, Puurs WSL10 1.3 mL fill, 10 µg dose. Supportive Stability	Oct 2021	-20 °C: 1 month (Complete) ^a	Table 3.2.P.8.3-13
			5 °C: 3 months ^b	Table 3.2.P.8.3-33
FK5132 (multi-dose)	Process Performance Qualification, Puurs WSL9 2.25 mL fill, 30 µg dose. Supportive Stability	Oct 2021	-20 °C: 1 month (Complete) ^a	Table 3.2.P.8.3-14
			5 °C: 3 months	Table 3.2.P.8.3-34
FM0703 (multi-dose)	Process Performance Qualification, Puurs WSL9 1.3 mL fill, 10 µg dose. Supportive Stability	Nov 2021	-20 °C: 1 month (Complete) ^a	Table 3.2.P.8.3-15
			5 °C: 3 months ^b	Table 3.2.P.8.3-35
2F1001A	Process Performance Qualification, (BioNTech Marburg/Sanofi) 2.25 mL Fill, 30 µg dose. Supportive Stability	Jan 2022	-20 °C: 2 weeks	Table 3.2.P.8.3-22
			5 °C: 2 weeks	Table 3.2.P.8.3-42
2F1003A	Process Performance Qualification, (BioNTech Marburg/Sanofi) 2.25 mL Fill, 30 µg dose. Supportive Stability	Jan 2022	-20 °C: 2 weeks	Table 3.2.P.8.3-23
			5 °C: 2 weeks	Table 3.2.P.8.3-43
FP8748	Process Performance Qualification, Puurs WSL5 2.25 mL Fill, 30 µg dose. Supportive Stability	Jan 2022	-20 °C: 1 month (Complete)	Table 3.2.P.8.3-16
			5 °C: 1 month	Table 3.2.P.8.3-36
2F1004A	Process Performance Qualification, (BioNTech Marburg/Sanofi) 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-20 °C: Release	Table 3.2.P.8.3-24
			5 °C: Release	Table 3.2.P.8.3-44
FR5013	Process Performance Qualification Puurs VC2 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-20 °C: 1 month (Complete)	Table 3.2.P.8.3-17
			5 °C: 1 month	Table 3.2.P.8.3-37
FR7348	Process Performance Qualification Puurs WSL10 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-20 °C: 1 month (Complete)	Table 3.2.P.8.3-18
			5 °C: 1 month ^b	Table 3.2.P.8.3-38
FW1374	Process Performance Qualification Puurs WSL7 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-20 °C: 1 month ^b	Table 3.2.P.8.3-19
			5 °C: 1 month ^b	Table 3.2.P.8.3-39
GA5554	Process Performance Qualification Puurs – 70 g RNA 2.25 mL Fill, 30 µg dose. Supportive Stability	Apr 2022	-20 °C: t0 data available	Table 3.2.P.8.3-20
			5 °C: t0 data available	Table 3.2.P.8.3-40

Table 3.2.P.8.3-1. Summary of Tris/Sucrose Drug Product Stability Studies for Additional Storage Conditions

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Data Table Location
FY3701	Process Performance Qualification Puurs – 220 g RNA 2.25 mL Fill, 30 µg dose. Supportive Stability	Mar 2022	-20 °C: t0 data available	Table 3.2.P.8.3-21
			5 °C: t0 data available	Table 3.2.P.8.3-41

- a. Terminated early, at indicated timepoint as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).
- b. Only partial data presented for last tested time point.
- c. Bulk drug product lot FJ5026 was split into two 800 L portions for separate filling as lots FJ5682 and FJ5683. Lot FJ5682 was not enrolled into the stability program.

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3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-2. Stability Data for Tris/Sucrose SDV Primary Drug Product Lot EX0490 Stored at $-50 \pm 5^\circ\text{C}$

Time	Appearance		pH	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 \pm 0.5				
0	WOS	Meets					
1M	WOS	Meets (EFVP)					

Time	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^a						4.2 1st ind
0						
1M						

a. Acceptance criteria in place at time of testing.

b. Assay run for information only.

M = Month, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, SDV = Single Dose Vial

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3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-3. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4564 Stored at -50 ± 5 °C

Time	Appearance		pH	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	4.2 1st ind			
0	WOS	Meets	7.3				
1M	WOS	Meets (EFVP)	7.3				

Time	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^a	4.2 1st Ind					RNA Integrity
0						
1M						

a. Acceptance criteria in place at time of testing.

b. Assay run for information only.

M = Month, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, MDV = Multi-dose Vial

Table 3.2.P.8.3-4. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 Stored at -50 ± 5 °C

Time	Appearance		pH	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	4.2 1st ind			
0	WOS	Meets	7.4				
1M	WOS	Meets (EFVP)	7.4				

Time	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	4.2 1st ind					
0						
1M						

a. Acceptance criteria in place at time of testing.

b. Assay run for information only.

M = Month, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, MDV = Multi-dose Vial

Table 3.2.P.8.3-5. Stability Data for Tris/Sucrose SDV Primary Drug Product Lot EX0490 Stored at $-20 \pm 5^\circ\text{C}$

Time ^a	Appearance		pH	Subvisible Particles ^c	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	$\geq 10 \mu\text{m}$: $\leq 6000/\text{container}$ $\geq 25 \mu\text{m}$: $\leq 600/\text{container}$	4.2 1st ind			
0	WOS	Meets	7.3					
1M	WOS	Meets (EFVP)	7.2					
2M	WOS	Meets (EFVP)	7.2					
3M	WOS	Meets (EFVP)	7.2					
4M	WOS	Meets (EFVP)	7.0					
5M	WOS	Meets (EFVP)	7.1					
6M	WOS	Meets (EFVP)	7.1					

Time ^a	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 ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass	
0										
1M										
2M										
3M										
4M										
5M										
6M										

a. Study terminated at 6 months storage as results demonstrated limited stability at $-20 \pm 5^\circ\text{C}$. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

c. Subvisible particles are reported per container.

d. Assay run for information only.

M = Month, NS = Not Scheduled at Time Point, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, SDV = Single Dose Vial

Table 3.2.P.8.3-6. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4564 Stored at -20 ± 5 °C

Time ^a	Appearance		pH	Subvisible Particles ^c	Dynamic Light Scattering (DLS)		Fluorescence Assay		
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content	
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind				
0	WOS	Meets	7.3	4.2 1st ind	4.2 1st ind				
1M	WOS	Meets (EFVP)	7.3	NS	4.2 1st ind				
2M	WOS	Meets (EFVP)	7.1	NS	4.2 1st ind				
3M	WOS	Meets (EFVP)	7.3	4.2 1st ind	4.2 1st ind				
4M	WOS	Meets (EFVP)	7.2	NS	4.2 1st ind				
5M	WOS	Meets (EFVP)	7.3	NS	4.2 1st ind				
6M	WOS	Meets (EFVP)	7.2	4.2 1st ind	4.2 1st ind				
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					
Acceptance Criteria	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0									
1M									
2M									
3M									
4M									
5M									
6M									

a. Study terminated at 6 months storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

c. Subvisible particles are reported per container.

d. Assay run for information only

M = Month, NS = Not Scheduled at Time Point, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, MDV = Multi Dose Vial

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3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-7. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 Stored at -20 ± 5 °C

Time ^a	Appearance		pH	Subvisible Particles ^c	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates			LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	≥10 µm: ≤6000/container ≥25 µm: ≤6000/container				
0	WOS	Meets	7.4	4.2 1st ind				4.2 1st ind
1M	WOS	Meets (EFVP)	7.4	NS				
2M	WOS	Meets (EFVP)	7.3	NS				
3M	WOS	Meets (EFVP)	7.3	4.2 1st ind				
4M	WOS	Meets (EFVP)	7.3	NS				
5M	WOS	Meets (EFVP)	7.3	NS				
6M	WOS	Meets (EFVP)	7.3	4.2 1st ind				

Table 3.2.P.8.3-7. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 Stored at $-20 \pm 5^{\circ}\text{C}$

Time ^a	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 ^b						4.2 1st ind	4.2 1st ind	No growth detected	Pass	
0								Pass	NS	
1M								NS	NS	
2M								NS	NS	
3M								4.2 1st ind	NS	Pass
4M								NS	NS	NS
5M		NS	NS	NS	NS					
6M		4.2 1st ind				NS	Pass			

a. Study terminated at 6 months storage as results demonstrated limited stability at $-20 \pm 5^{\circ}\text{C}$. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

c. Subvisible particles are reported per container

d. Assay run for information only.

M = Month, NS = Not Scheduled at Time Point, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, MDV = Multi-dose Vial

Table 3.2.P.8.3-8. Stability Data for Tris/Sucrose MDV Process Performance Qualification Drug Product Lot FC8273 – FC1 - 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				
3M	Meets	Meets	7.4				

Time ^a	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 ^b	4.2 1st ind						4.2 1st ind
0							
1M							
3M							

a. Study terminated at 3 months storage as results demonstrated limited stability at -20 ± 5 °C. See Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose.

b. Acceptance criteria in place at time of testing.

M = Month, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-9. Stability Data for Tris/Sucrose MDV Process Performance Qualification Drug Product Lot FE4394 – FC2 - 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white, opaque, amorphous particles	7.4 ± 0.5				4.2 1st ind
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b						4.2 1st ind
0						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-10. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FJ5683 – FC1 - 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind
0						
1M						

a. Study terminated at 1 months storage as results demonstrated limited stability at -20 ± 5 °C. See Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose.

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-11. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot**FK5127 – WSL10, 1.3 mL Fill, 10 µg Dose - Stored at $-20 \pm 5^{\circ}\text{C}$**

Time ^a	Appearance ^b		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD					Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content			
Acceptance Criteria ^b	4.2 1st ind					4.2 1st ind	4.2 1st ind
0							
1M							

a. Study terminated at 1 month storage as results demonstrated limited stability at $-20 \pm 5^{\circ}\text{C}$. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-12. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot**FK5128 – WSL10 – 0.4 mL Fill, 3 µg Dose – Stored at -20 ± 5 °C**

Time ^a	Appearance ^b		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry		Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity	
Acceptance Criteria ^b	4.2 1st ind						4.2 1st ind
0							
1M							

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-13. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot**FK5618 – WSL10 - 1.3 mL Fill, 10 µg Dose - Stored at -20 ± 5 °C**

Time ^a	Appearance ^b		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	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 ^b	4.2 1st ind					
0						
1M						

a. Study terminated at 1 months storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-14. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5132 – WSL9 - 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance ^a		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5				4.2 1st ind
0	Meets	Meets	7.4				
1M	Meets	Meets	7.5				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b						4.2 1st ind
0						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-15. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot**FM0703 – WSL9 - 1.3 mL Fill, 10 µg Dose - Stored at -20 ± 5 °C**

Time ^a	Appearance ^b		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind
0						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-16. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FP8748-WS15 – 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance ^a		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.5				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind
0						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-17. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FR5013 – VC2 – 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance ^c		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0 ^c	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind
0 ^c						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

c. Analysis for T0 was repeated for this study. Initial data (T0) of batch FR5013 is not from release testing, with the exception of IVE.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-18. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FR7348 – WSL10 – 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance ^a		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets test	Meets test	7.4				
1M	Meets test	Meets test	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind
0						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-19. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FW1374 – WSL7 – 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance ^a		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	Meets	Meets	7.4				

Time ^a	HPLC-CAD				Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content		
Acceptance Criteria ^b	4.2 1st ind				4.2 1st ind	4.2 1st ind
0						
1M						

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-20. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot GA5554 – 70 g RNA – 2.25 mL Fill, 30 µg Dose - Stored at $-20 \pm 5^{\circ}\text{C}$

Time ^a	Appearance ^a		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.5				
1M	S	S	S	S	S	S	S

Time ^a	HPLC-CAD					Cell-based Flow Cytometry		Capillary Gel Electrophoresis	
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	In Vitro Expression	RNA Integrity	RNA Integrity	RNA Integrity
Acceptance Criteria ^b	4.2 1st ind					4.2 1st ind			
0									
1M									

a. Study terminated at 1 month storage as results demonstrated limited stability at $-20 \pm 5^{\circ}\text{C}$. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-21. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FY3701 – 220 g RNA – 2.25 mL Fill, 30 µg Dose - Stored at -20 ± 5 °C

Time ^a	Appearance ^b		pH	Dynamic Light Scattering (DLS)		Fluorescence Assay	
	Appearance (Visible)	Visible Particulates		LNP Size	LNP Polydispersity	RNA Encapsulation	RNA Content
Acceptance Criteria ^b	White to off-white suspension	May contain white to off-white opaque, amorphous particles	7.4 ± 0.5	4.2 1st ind			
0	Meets	Meets	7.4				
1M	S	S	S	S	S	S	S

Time ^a	HPLC-CAD					Cell-based Flow Cytometry		Capillary Gel Electrophoresis	
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	In Vitro Expression	RNA Integrity	RNA Integrity	RNA Integrity
Acceptance Criteria ^b	4.2 1st ind					4.2 1st ind			
0									
1M									

a. Study terminated at 1 month storage as results demonstrated limited stability at -20 ± 5 °C. See [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

b. Acceptance criteria in place at time of testing.

M = Month, S = To be Scheduled, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial

Table 3.2.P.8.3-22. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1001A – 2.25 mL Fill, 30 µg dose - Stored Inverted at -20 ± 5 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Complies	Complies	7.4					
2W	Complies	Complies	7.5					
1M	S	S	S	S	S	S	S	S
3M	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	4.2 1st ind				S	S	4.2 1st ind	No growth detected	Pass	
0										
2W										
1M	S	S	S	S	S	S	NS	NS	NS	NS
3M	S	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. Previously approved method, which uses different RNA concentrations in the sample preparation for encapsulated RNA and total RNA.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-23. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1003A – 2.25 mL Fill, 30 µg dose - Stored Inverted at -20 ± 5 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container				4.2 1st ind
0	Complies	Complies	7.4	4.2 1st ind				
2W	Complies	Complies	7.4					
1M	S	S	S	S	S	S	S	S
3M	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						4.2 1st ind	4.2 1st ind	No growth detected	Pass
0								NGD	Pass
2W							NS	NS	NS
1M	S	S	S	S	S		NS	NS	NS
3M	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. Previously approved method, which uses different RNA concentrations in the sample preparation for encapsulated RNA and total RNA.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-24. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1004A – 2.25 mL Fill, 30 µg dose – Stored Inverted at -20 ± 5 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Complies	Complies	7.4					
2W	Complies	Complies	7.5					
1M	S	S	S	S	S	S	S	S
3M	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	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass	Pass
0										
2W										
1M	S	S	S	S	S	S	NS	NS	NS	NS
3M	S	S	S	S	S	S	NS	NS	NS	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

c. Previously approved method, which uses different RNA concentrations in the sample preparation for encapsulated RNA and total RNA.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-25. Stability Data for Tris/Sucrose SDV Primary Drug Product Lot EX0490 Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container				4.2 1st ind
0	WOS	Meets	7.3	4.2 1st ind				
2W	WOS	Meets (EFVP)	7.3	NS				
1M	WOS	Meets (EFVP)	7.2	NS				
6W	WOS	Meets (EFVP)	7.3	NS				
2M	WOS	Meets (EFVP)	7.2	NS				
3M	WOS	Meets (EFVP)	7.2	NS				
4M	WOS	Meets (EFVP)	7.1	NS				
5M	WOS	Meets (EFVP)	7.2	NS				
6M	WOS	Meets (EFVP)	7.2	4.2 1st ind				

Time	HPLC-CAD			Cholesterol Content	Cell-based Flow Cytometry In Vitro Expression	Capillary Gel Electrophoresis RNA Integrity
	ALC-0315 Content	ALC-0159 Content	DSPC Content			
Acceptance Criteria ^a		4.2 1st ind				4.2 1st ind
0						
2W						
1M						
6W						
2M						
3M						
4M						
5M						
6M						

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

c. Assay run for information only.

W = Week, M = Month, NS = Not Scheduled at Time Point, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, SDV = Single Dose Vial

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3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-26. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4564 Stored at $5 \pm 3^\circ\text{C}$

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	$\geq 10 \mu\text{m}$: $\leq 6000/\text{container}$ $\geq 25 \mu\text{m}$: $\leq 600/\text{container}$	4.2 1st ind			
0	WOS	Meets	7.3	4.2 1st ind				
2W	WOS	Meets (EFVP)	7.4	NS				
1M	WOS	Meets (EFVP)	7.3	NS				
6W	WOS	Meets (EFVP)	7.3	NS				
2M	WOS	Meets (EFVP)	7.3	NS				
3M	WOS	Meets (EFVP)	7.3	NS				
4M	WOS	Meets (EFVP)	7.3	NS				
5M	WOS	Meets (EFVP)	7.3	NS				
6M	WOS	Meets (EFVP)	7.3	4.2 1st ind				
Time	HPLC-CAD				Cell-based Flow Cytometry		Capillary Gel Electrophoresis	
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression	RNA Integrity	RNA Integrity	RNA Integrity

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3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-26. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4564 Stored at 5 ± 3 °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	4.2 1st ind							
0								
2W								
1M								
6W								
2M								
3M								
4M								
5M								
6M								

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

c. Assay run for information only.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, MDV = Multi-dose Vial

BNT162b2

3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-27. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 Stored at 5 ± 3 °C

Time	Appearance ^a		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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	WOS	Meets	7.4	4.2 1st ind				
2W	WOS	Meets (EFVP)	7.4	NS				
1M	WOS	Meets (EFVP)	7.4	NS				
6W	WOS	Meets (EFVP)	7.3	NS				
2M	WOS	Meets (EFVP)	7.2	NS				
3M	WOS	Meets (EFVP)	7.3	NS				
4M	WOS	Meets (EFVP)	7.3	NS				
5M	WOS	Meets (EFVP)	7.4	NS				
6M	WOS	Meets (EFVP)	7.3	4.2 1st ind	4.2 1st ind			
Time	HPLC-CAD							
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content	In Vitro Expression		RNA Integrity	

BNT162b2

3.2.P.8.3. Stability Data – Additional Storage Conditions – Tris-Sucrose

Table 3.2.P.8.3-27. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 Stored at $5 \pm 3^\circ\text{C}$

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								4.2
0								1st ind
2W								
1M								
6W								
2M								
3M								
4M								
5M								
6M								

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

c. Assay run for information only.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, EFVP = Essentially free from visible particulates, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, MDV = Multi-dose Vial

Table 3.2.P.8.3-28. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FC8273 – FC1 - 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind		4.2 1st ind	
0	Meets	Meets	7.4					
1M	Meets	Meets	7.4					
3M	Meets	Meets	7.4					
6M	Meets	Meets	7.4					
12M	S	S	S	S	Pending	Pending	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0									
1M									
3M									
6M									
12M	S	S	S	S	Pending	S	S	S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-29. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FE4394 – FC2 - 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container		4.2 1st ind		4.2 1st ind
0	Meets	Meets	7.4	4.2 1st ind				
1M	Meets	Meets	7.4	NS				
3M	Meets	Meets	7.4	NS				
6M	Meets	Meets	7.4	4.2 1st ind	Pending	Pending		
12M	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						
Acceptance Criteria ^a				4.2 1st ind	4.2 1st ind		4.2 1st ind	4.2 1st ind	No growth detected	Container Closure Integrity Pass
0									NGD	Pass
1M								NS	NS	NS
3M								NS	NS	NS
6M								NS	NS	NS
12M	S	S	S	S	S	Pending	S	S	S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-30. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FJ5683 – FC1 - 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4					
1M	Meets	Meets	7.4	NS				
3M	Meets	Meets	7.4	NS				
6M	S	S	S	S	S	S	S	S
12M	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					
Acceptance Criteria ^a	4.2 1st ind					4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0										
1M										
3M										
6M	S	S	S	S	Pending	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-31. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5127 – WSL10 - 1.3 mL Fill, 10 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4					
1M	Meets	Meets	7.4	NS				
3M	Meets	Meets	7.4	NS				
6M	S	S	S	S	S	S	S	S
12M	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	
Acceptance Criteria ^a	4.2 1st ind					4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass		
0												
1M												
3M												
6M	S	S	S	S	Pending	S	S	NS	NS	NS		
12M	S	S	S	S	S	S	S	S	S	S		

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-32. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5128 – WSL10 - 0.4 mL Fill, 3 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4					
1M	Meets	Meets	7.4	NS				
3M	Meets	Meets	7.4	NS				
6M	S	S	S	S	S	S	S	S
12M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0					Pending	S	S	NGD	Pass
1M								NS	NS
3M								NS	NS
6M								NS	NS
12M	S	S	S	S				NS	NS
	S	S	S	S				S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-33. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5618 – WSL10 - 1.3 mL Fill, 10 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4					
1M	Meets	Meets	7.4	NS				
3M	Meets	Meets	7.4	NS				
6M	S	S	S	S	S	S	S	
12M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0					Pending			NGD	Pass
1M							NS	NS	NS
3M							NS	NS	NS
6M	S	S	S	S			NS	NS	NS
12M	S	S	S	S			S	S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-34. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5132 – WSL9 - 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4	4.2 1st ind				
1M	Meets	Meets	7.5	NS				
3M	Meets	Meets	7.4	NS				
6M	S	S	S	S	S	S	S	S
12M	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	Pass
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass	Pass
0										
1M										
3M										
6M	S	S	S	S						
12M	S	S	S	S						

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-35. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FM0703 – WSL9 - 1.3 mL Fill, 10 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤6000/container	4.2 1st ind			
0	Meets	Meets	7.4					
1M	Meets	Meets	7.4	NS				
3M	Meets	Meets	7.5	NS				
6M	S	S	S	S	S	S	S	S
12M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Container Closure Integrity Pass
0					Pending	S	S	NGD	Pass
1M								NS	NS
3M								NS	NS
6M	S	S	S	S				NS	NS
12M	S	S	S	S				NS	NS

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-36. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FP8748 – WSL5 – 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4					
1M	Meets	Meets	7.5	NS				
3M	S	S	S	NS	S	S	S	S
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S

Time	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis RNA Integrity	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0									
1M									
3M	S	S	S	S					
6M	S	S	S	S					
12M	S	S	S	S					

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-37. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FR5013 – VC2 – 2.25 mL Fill, 30 µg Dose – Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0 ^c	Meets test	Meets test	7.4	4.2 1st ind				
1M	Meets test	Meets test	7.5	NS				
3M	S	S	S	NS	S	S	S	S
6M	S	S	S	S	S	S	S	S
12M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0 ^c									
1M									
3M	S	S	S	S			NS	NS	NS
6M	S	S	S	S			NS	NS	NS
12M	S	S	S	S			NS	NS	NS
							S	S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

c. Analysis for T0 was repeated for this study. Initial data (T0) of batch FR5013 is not from release testing, with the exception of sterility, endotoxin, subvisible particles and IVE.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-38. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FR7348 – WSL10 – 2.25 mL Fill, 30 µg Dose – Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4					
1M	Meets test	Meets test	7.4	NS				
3M	S	S	S	NS	S	S	S	S
6M	S	S	S	S	S	S	S	S
12M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Container Closure Integrity Pass
0									
1M									
3M	S	S	S	S					
6M	S	S	S	S					
12M	S	S	S	S					

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To Be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-39. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FW1374 – WSL7 – 2.25 mL Fill, 30 µg Dose – Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4	4.2 1st ind				
1M	Meets test	Meets test	7.4	NS				
3M	S	S	S	NS	S	S	S	S
6M	S	S	S	S	S	S	S	S
12M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0									
1M									
3M	S	S	S	S					
6M	S	S	S	S					
12M	S	S	S	S					

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To Be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-40. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot GA5554 – 70 g RNA – 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.5					
1M	S	S	S	NS				
3M	S	S	S	NS				
6M	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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	No growth detected	No growth detected	Pass
0									
1M	S	S	S	S					
3M	S	S	S	S					
6M	S	S	S	S					

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To Be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-41. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FY3701 – 220 g RNA – 2.25 mL Fill, 30 µg Dose - Stored at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4					
1M	S	S	S	NS				
3M	S	S	S	NS				
6M	S	S	S	S				

Time	HPLC-CAD				Cell-based Flow Cytometry	Capillary Gel Electrophoresis RNA Integrity	Endotoxin (LAL)	Sterility	Dye Incursion
	ALC-0315 Content	ALC-0159 Content	DSPC Content	Cholesterol Content					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Container Closure Integrity
0									Pass
1M	S	S	S	S					Meets test
3M	S	S	S	S					NS
6M	S	S	S	S					NS

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-42. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1001A – 2.25 mL Fill, 30 µg dose - Stored Inverted at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Complies	Complies	7.4					
2W	Complies	Complies	7.5					
1M	S	S	S	S	S	S	S	S
3M	S	S	S	S	S	S	S	S
6M	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	Pass
Acceptance Criteria ^a	4.2 1st ind							4.2 1st ind	No growth detected	Pass	
0									NGD	Pass	
2W								NS	NS	NS	
1M	S	S	S	S	S			NS	NS	NS	
3M	S	S	S	S	S			S	S	S	
6M	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. Previously approved method, which uses different RNA concentrations in the sample preparation for encapsulated RNA and total RNA.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-43. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1003A – 2.25 mL Fill, 30 µg dose - Stored Inverted at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Complies	Complies	7.4	4.2 1st ind				
2W	Complies	Complies	7.4					
1M	S	S	S	S	S	S	S	S
3M	S	S	S	S	S	S	S	S
6M	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	Pass
Acceptance Criteria ^a	4.2 1st ind					4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass	Pass
0											
2W											
1M	S	S	S	S	S						
3M	S	S	S	S	S						
6M	S	S	S	S	S						

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

c. Previously approved method, which uses different RNA concentrations in the sample preparation for encapsulated RNA and total RNA.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-44. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1004A – 2.25 mL Fill, 30 µg dose - Stored Inverted at 5 ± 3 °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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Complies	Complies	7.4					
2W	Complies	Complies	7.5					
1M	S	S	S	S	S	S	S	
3M	S	S	S	S	S	S	S	
6M	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	Pass
Acceptance Criteria ^a	4.2 1st ind					4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass	Pass
0											
2W											
1M	S	S	S	S	S	S	S	NS	NS	NS	NS
3M	S	S	S	S	S	S	S	NS	NS	NS	NS
6M	S	S	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. Previously approved method, which uses different RNA concentrations in the sample preparation for encapsulated RNA and total RNA.

W = Week, M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, MDV = Multi-Dose Vial, NGD = No Growth Detected