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3.2.P.8.3. STABILITY DATA – LONG-TERM STORAGE – TRIS/SUCROSE DRUG PRODUCT

Data from stability studies on BNT162b2 Tris/Sucrose drug product lots stored at the long-term storage condition of -90 to -60 °C are presented in this section. A list of the studies and available data are provided in [Table 3.2.P.8.3-1](#). The results are discussed further in [Section 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose](#).

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

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Table Location
EX0490 (single dose)	Primary Stability	March 2021	-90 to -60 °C: 9 months	Table 3.2.P.8.3-2
EW4564 (multi-dose)	Primary Stability	April 2021	-90 to -60 °C: 9 months	Table 3.2.P.8.3-3
EW4565 (multi-dose)	Primary Stability	April 2021	-90 to -60 °C: 9 months	Table 3.2.P.8.3-4
FC8273 (multi-dose)	Process Performance Qualification, Puurs FC1 2.25 mL Fill, 30 µg dose. Supportive Stability	June 2021	-90 to -60 °C: 6 Months	Table 3.2.P.8.3-5
FE4394 (multi-dose)	Process Performance Qualification, Puurs FC2 2.25 mL Fill, 30 µg dose. Supportive Stability	July 2021	-90 to -60 °C: 6 months ^b	Table 3.2.P.8.3-6
FJ5683 ^a (multi-dose)	Process Performance Qualification, Puurs FC1 2.25 mL Fill, 30 µg dose. Supportive Stability	Aug 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-7
FK5127 (multi-dose)	Process Performance Qualification, Puurs WSL10 1.3 mL fill, 10 µg dose. Supportive Stability	Sep 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-8
FK5128 (multi-dose)	Process Performance Qualification, Puurs WSL10 0.4 mL fill, 3 µg dose. Supportive Stability	Sep 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-9
FK5618 (multi-dose)	Process Performance Qualification, Puurs WSL10 1.3 mL fill, 10 µg dose. Supportive Stability	Oct 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-10
FK5132 (multi-dose)	Process Performance Qualification, Puurs WSL9 2.25 mL Fill, 30 µg dose. Supportive Stability	Oct 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-11
FM0703 (multi-dose)	Process Performance Qualification, Puurs WSL9 1.3 mL fill, 10 µg dose. Supportive Stability	Nov 2021	-90 to -60 °C: 3 months	Table 3.2.P.8.3-12
2F1001A	Process Performance Qualification, (BioNTech Marburg/Sanofi) 2.25 mL Fill, 30 µg dose. Supportive Stability	Jan 2022	-90 to -60 °C: 2 weeks	Table 3.2.P.8.3-19
2F1003A	Process Performance Qualification, (BioNTech Marburg/Sanofi) 2.25 mL Fill, 30 µg dose. Supportive Stability	Jan 2022	-90 to -60 °C: 2 weeks	Table 3.2.P.8.3-20

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

Lot Number	Drug Product Lot Use	Stability Study Start	Stability Data Presented	Table Location
FP8748	Process Performance Qualification, Puurs WSL5 2.25 mL Fill, 30 µg dose. Supportive Stability	Jan 2022	-90 to -60 °C: 1 month ^b	Table 3.2.P.8.3-13
FR5013	Process Performance Qualification Puurs VC2 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-90 to -60 °C: 1 month	Table 3.2.P.8.3-14
2F1004A	Process Performance Qualification (BioNTech Marburg/Sanofi) 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-90 to -60 °C: 2 weeks	Table 3.2.P.8.3-21
FR7348	Process Performance Qualification Puurs WSL10 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-90 to -60 °C: 1 month	Table 3.2.P.8.3-15
FW1374	Process Performance Qualification Puurs WSL7 2.25 mL Fill, 30 µg dose. Supportive Stability	Feb 2022	-90 to -60 °C: 1 month ^b	Table 3.2.P.8.3-16
GA5554	Process Performance Qualification Puurs – 70 g RNA 2.25 mL Fill, 30 µg dose. Supportive Stability	Apr 2022	-90 to -60 °C: t0 data available ^b	Table 3.2.P.8.3-17
FY3701	Process Performance Qualification Puurs – 220 g RNA 2.25 mL Fill, 30 µg dose. Supportive Stability	Mar 2022	-90 to -60 °C: t0 data available	Table 3.2.P.8.3-18

a. 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.

b. Only partial data available for last time point tested

Abbreviations: FC1 = Focus Cell 1 filling line; FC2 = Focus Cell 2 filling line; WSL9 = Washing and Sterilizing Line 9; WSL5 = Washing and Sterilizing Line 5; VC2 = Vaccine Cell 2 filling line; WSL10 = Washing and Sterilizing Line 10; WSL7 = Washing and Sterilizing Line 7

Table 3.2.P.8.3-2. Stability Data for Tris/Sucrose SDV Primary Drug Product Lot EX0490 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	WOS	Meets	7.3	4.2 1st ind				
1M	WOS	Meets (EFVP)	7.3	NS	4.2 1st ind			
2M	WOS	Meets (EFVP)	7.2	NS				
3M	WOS	Meets (EFVP)	7.2	4.2 1st ind	4.2 1st ind			
4M	WOS	Meets (EFVP)	7.3	NS				
5M	WOS	Meets (EFVP)	7.1	NS	4.2 1st ind			
6M	WOS	Meets (EFVP)	7.2	4.2 1st ind				
9M	WOS	Meets (EFVP)	7.2	NS	4.2 1st ind			
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

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

Table 3.2.P.8.3-2. Stability Data for Tris/Sucrose SDV Primary Drug Product Lot EX0490 Stored at -90 to -60 °C

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								No growth detected	Pass	
0											
1M									NS	NS	
2M									NS	NS	
3M									NS	NS	
4M									4.2 1st ind	NS	NS
5M									NS	NS	NS
6M									4.2 1st ind	NS	Pass
9M									NS	NS	NS
12M	S	S	S	S	S	S	S	S			
18M	S	S	S	S	S	NS	NS	NS			
24M	S	S	S	S	S	S	S	S			

a. Acceptance criteria in place at time of testing.

b. Assay run for information only.

c. Cell-based flow cytometry inadvertently not tested at the 1M time point.

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

Table 3.2.P.8.3-3. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4564 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	WOS	Meets	7.3	4.2 1st ind				
1M	WOS	Meets (EFVP)	7.3	NS	4.2 1st ind			
2M	WOS	Meets (EFVP)	7.2	NS				
3M	WOS	Meets (EFVP)	7.3	4.2 1st ind	4.2 1st ind			
4M	WOS	Meets (EFVP)	7.2	NS				
5M	WOS	Meets (EFVP)	7.4	NS	4.2 1st ind			
6M	WOS	Meets (EFVP)	7.3	4.2 1st ind				
9M	WOS	Meets (EFVP)	7.3	NS	S	S	S	S
12M	S	S	S	S				
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

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

Table 3.2.P.8.3-3. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4564 Stored at -90 to -60 °C

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						RNA Integrity		
Acceptance Criteria ^a	4.2 1st ind								No growth detected	Pass		
0												
1M									NS	NS		
2M												
3M									4.2 1st ind	NS	NS	Pass
4M												
5M									NS	NS		
6M												
9M									4.2 1st ind	NS	NS	Pass
12M												
18M									S	S	S	S
24M												

a. Acceptance criteria in place at time of testing.

b. Assay run for information only.

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

Table 3.2.P.8.3-4. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 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					
0	WOS	Meets	7.4					
1M	WOS	Meets (EFVP)	7.4					
2M	WOS	Meets (EFVP)	7.2					
3M	WOS	Meets (EFVP)	7.3					
4M	WOS	Meets (EFVP)	7.2					
5M	WOS	Meets (EFVP)	7.4					
6M	WOS	Meets (EFVP)	7.3					
9M	WOS	Meets (EFVP)	7.3					
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

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, WOS = White to off-white suspension, EFVP = Essentially free from visible particulates, MDV = Multi-Dose Vial

Table 3.2.P.8.3-4. Stability Data for Tris/Sucrose MDV Primary Drug Product Lot EW4565 Stored at -90 to -60 °C

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							No growth detected	Pass	
0										
1M										
2M										
3M										
4M										
5M										
6M										
9M										
12M										
18M	S	S	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S	S	S

a. Acceptance criteria in place at time of testing.

b. Assay was run for information only

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

Table 3.2.P.8.3-5. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FC8273 – FC1 – 2.25 mL Fill, 30 µg dose – 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4	4.2 1st ind	4.2 1st ind			
4M ^c	Meets	Meets	7.4	4.2 1st ind	4.2 1st ind			
6M	Meets	Meets	7.5	4.2 1st ind	4.2 1st ind			
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					
Acceptance Criteria ^a	4.2 1st ind						4.2 1st ind	No growth detected	Pass
0							4.2 1st ind		
4M c							4.2 1st ind		
6M							4.2 1st ind		
12M	S	S	S	S	S	S	NS	NS	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. Additional timepoint evaluated.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, EFVP = Essentially free from visible particulates, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-6. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FE4394 – FC2 - 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4					
4M c	Meets	Meets	7.4					
6M	Meets	Meets	7.4					
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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				No growth detected
0									
4M c									
6M									
12M	S	S	S	S	S	S	NS	NS	NS
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. Additional timepoint evaluated.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, EFVP = Essentially free from visible particulates, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-7. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FJ5683 – FC1 - 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4	NS	4.2	1st ind	4.2	1st ind
1M ^c	Meets	Meets	7.4	NS	4.2	1st ind	4.2	1st ind
3M ^c	Meets	Meets	7.4	NS	4.2	1st ind	4.2	1st ind
6M	S	S	S	S	4.2	1st ind	4.2	1st ind
12M	S	S	S	S	4.2	1st ind	4.2	1st ind
18M	S	S	S	S	4.2	1st ind	4.2	1st ind
24M	S	S	S	S	4.2	1st ind	4.2	1st ind

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					In Vitro Expression	RNA Integrity	No growth detected	Pass
0									
1M ^c									
3M ^c									
6M	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. Additional timepoint evaluated.

M = Month, S = To be Scheduled, NS = Not Scheduled at Time Point, LNP = Lipid Nanoparticle, WOS = White to off-white suspension, EFVP = Essentially free from visible particulates, MDV = Multi-Dose Vial, NGD = No Growth Detected

Table 3.2.P.8.3-8. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5127 – WSL10, 1.3 mL Fill, 10 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4		4.2 1st ind			
1M ^c	Meets	Meets	7.4	NS	4.2 1st ind			
3M ^c	Meets	Meets	7.4	NS	4.2 1st ind			
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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	No growth detected	Pass
0										
1M ^c										
3M ^c										
6M										
12M	S	S	S	S	S	S	S	S	NS	NS
18M	S	S	S	S	S	S	S	NS	NS	NS
24M	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. Additional timepoint evaluated.

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.8.3-9. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5128–WSL10, 0.4 mL Fill, 3 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets	Meets	7.4	4.2 1st ind	4.2 1st ind			
1M ^c	Meets	Meets	7.4	NS	4.2 1st ind			
3M ^c	Meets	Meets	7.3	NS	4.2 1st ind			
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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				
0	4.2 1st ind					4.2 1st ind				
1M ^c	4.2 1st ind					NS				
3M ^c	4.2 1st ind					NS				
6M	S	S	S	S	S	S	S	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	NS	NS	NS
24M	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. Additional timepoint evaluated for stability.

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.8.3-10. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5618 – WSL10, 1.3 mL Fill, 10 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4		4.2 1st ind			
1M ^c	Meets test	Meets test	7.4	NS	4.2 1st ind			
3M ^c	Meets test	Meets test	7.4	NS	4.2 1st ind			
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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				No growth detected	Pass		
0													
1M ^c										Pass			
3M ^c										NS			
6M	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. Additional timepoint evaluated for stability

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.8.3-11. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FK5132 – WSL9, 2.25 mL Fill, 30 µg dose – 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4		4.2 1st ind			
1M c	Meets test	Meets test	7.5	NS	4.2 1st ind			
3M ^c	Meets test	Meets test	7.4	NS	4.2 1st ind			
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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						RNA Integrity
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind				Pass
0	4.2 1st ind				4.2 1st ind					Pass
1M c	4.2 1st ind				4.2 1st ind					NS
3M ^c	4.2 1st ind				4.2 1st ind					NS
6M	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. Additional timepoint tested

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.8.3-12. Stability Data for Tris/Sucrose MDV Process Performance Qualification Puurs Drug Product Lot FM0703 – WSL9, 1.3 mL Fill, 10 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4		4.2 1st ind			
1M ^c	Meets test	Meets test	7.4	NS	4.2 1st ind			
3M ^c	Meets test	Meets test	7.5	NS	4.2 1st ind			
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

Time	HPLC-CAD				Cell-based Flow Cytometry ^b	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	No growth detected	Container Closure Integrity Pass
0	4.2 1st ind						4.2 1st ind	NGD	Pass
1M ^c	4.2 1st ind						NS	NS	NS
3M ^c	4.2 1st ind						NS	NS	NS
6M	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. Additional timepoint tested

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.8.3-13. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FP8748 – WSL5, 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4		4.2 1st ind			
1M ^c	Meets test	Meets test	7.3	NS	4.2 1st ind			
3M ^c	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
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					
Acceptance Criteria ^a	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	No growth detected	Pass
0	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	NGD	Pass
1M ^c	4.2 1st ind				4.2 1st ind	4.2 1st ind	4.2 1st ind	NS	NS
3M ^c	S	S	S	S	S	S	S	NS	NS
6M	S	S	S	S	S	S	S	NS	NS
12M	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	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. Additional timepoint tested

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.8.3-14. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FR5013–VC2, 2.25 mL Fill, 30 µg dose – 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind			
0 ^d	Meets test	Meets test	7.4	NS	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind			
1M ^e	Meets test	Meets test	7.4	NS	S	S	S	S
3M ^e	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
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						RNA Integrity
Acceptance Criteria ^a	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind								No growth detected	Pass
0 ^d	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind								NGD	Meets test
1M ^c	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind								NS	NS
3M ^c	S	S	S	S	S	S	NS	NS	NS	
6M	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. Additional timepoint tested

d. 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.8.3-15. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FR7348–WSL10, 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4	4.2 1st ind				
1M ^c	Meets test	Meets test	7.4	NS	4.2 1st ind			
3M ^c	S	S	S	NS				
6M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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	Meets test
0											
1M ^c	S	S	S	S	S	S	S	NS	NS	NS	NS
3M ^c	S	S	S	S	S	S	S	NS	NS	NS	NS
6M	S	S	S	S	S	S	S	NS	NS	NS	NS
12M	S	S	S	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	NS	NS	NS	NS
24M	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. Additional timepoint tested

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.8.3-16. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FW1374-WSL7, 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind4.2 1st ind			
0	Meets test	Meets test	7.4	4.2 1st ind	4.2 1st ind4.2 1st ind			
1M ^c	Meets test	Meets test	7.4	NS	4.2 1st ind4.2 1st ind			
3M ^c	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
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							
Acceptance Criteria ^a	4.2 1st ind					4.2 1st ind				No growth detected	Pass
0											
1M ^c											
3M ^c											
6M	S	S	S	S	S	S	NS	NS	NS		
12M	S	S	S	S	S	S	S	S	NS		
18M	S	S	S	S	S	S	NS	NS	NS		
24M	S	S	S	S	S	S	S	S	S		

a. Acceptance criteria in place at time of testing.

b. Subvisible particles are reported per container.

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

Table 3.2.P.8.3-17. 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 -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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.5					
1M ^c	S	S	S	NS	S	S	S	
3M ^c	S	S	S	NS	S	S	S	
6M	S	S	S	S	S	S	S	
12M	S	S	S	S	S	S	S	
18M	S	S	S	S	S	S	S	
24M	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					
Acceptance Criteria ^a	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind					No growth detected			
0	4.2 1st ind4.2 1st ind4.2 1st ind4.2 1st ind					NGD			
1M ^c	S					NS			
3M ^c	S					NS			
6M	S					NS			
12M	S					S			
18M	S					NS			
24M	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.8.3-18. Stability Data for Tris/Sucrose Process Performance Qualification Puurs Drug Product Lot FY3701–220 gRNA, 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Meets test	Meets test	7.4					
1M ^c	S	S	S	NS				
3M ^c	S	S	S	NS				
6M	S	S	S	S				
12M	S	S	S	S				
18M	S	S	S	S				
24M	S	S	S	S				

Time	HPLC-CAD					Cell-based Flow Cytometry ^b	Capillary Gel Electrophoresis RNA Integrity	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 ^c										
3M ^c										
6M										
12M										
18M										
24M										

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.8.3-19. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1001A – 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container				
0	Complies	Complies	7.4					
2W	Complies	Complies	7.3					
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
9M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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.8.3-19. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1001A – 2.25 mL Fill, 30 µg dose - Stored at -90 to -60 °C

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				
0					4.2 1st ind				
2W	4.2 1st ind				NS				
1M					NS				
3M					NS				
6M					S				
9M					S				
12M					S				
18M					NS				
24M					S				
					S				
					S				

a. Acceptance criteria in place at time of testing.

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.8.3-20. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1003A – 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container	4.2 1st ind			
0	Complies	Complies	7.4					
2W	Complies	Complies	7.3					
1M	S	S	S	S				
3M	S	S	S	S				
6M	S	S	S	S				
9M	S	S	S	S				
12M	S	S	S	S				
18M	S	S	S	S				
24M	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.8.3-20. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1003A – 2.25 mL Fill, 30 µg dose - Stored at -90 to -60 °C

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	No growth detected	Pass
0							4.2 1st ind	NGD	Pass
2W									
1M	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	S	S	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. Acceptance criteria in place at time of testing.

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.8.3-21. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1004A – 2.25 mL Fill, 30 µg dose - 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	≥10 µm: ≤6000/container ≥25 µm: ≤600/container				
0	Complies	Complies	7.4					
2W	Complies	Complies	7.3					
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
9M	S	S	S	S	S	S	S	S
12M	S	S	S	S	S	S	S	S
18M	S	S	S	S	S	S	S	S
24M	S	S	S	S	S	S	S	S

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.8.3-21. Stability Data for Tris/Sucrose Process Performance Qualification BNT Marburg / Sanofi Drug Product Lot 2F1004A – 2.25 mL Fill, 30 µg dose - Stored at -90 to -60 °C

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								
0										4.2 1st ind			
2W													
1M													
3M	S	S	S	S	S	NS	NS	NS					
6M	S	S	S	S	S	NS	NS	NS					
9M	S	S	S	S	S	S	S	S					
12M	S	S	S	S	S	NS	NS	NS					
18M	S	S	S	S	S	S	S	NS					
24M	S	S	S	S	S	NS	NS	NS					
	S	S	S	S	S	S	S	S					

a. Acceptance criteria in place at time of testing.

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