

Dynamic Light Scattering, Salt Titration of
Histidine Buffer Exchanged ALXN1210 at 50 mg/mL

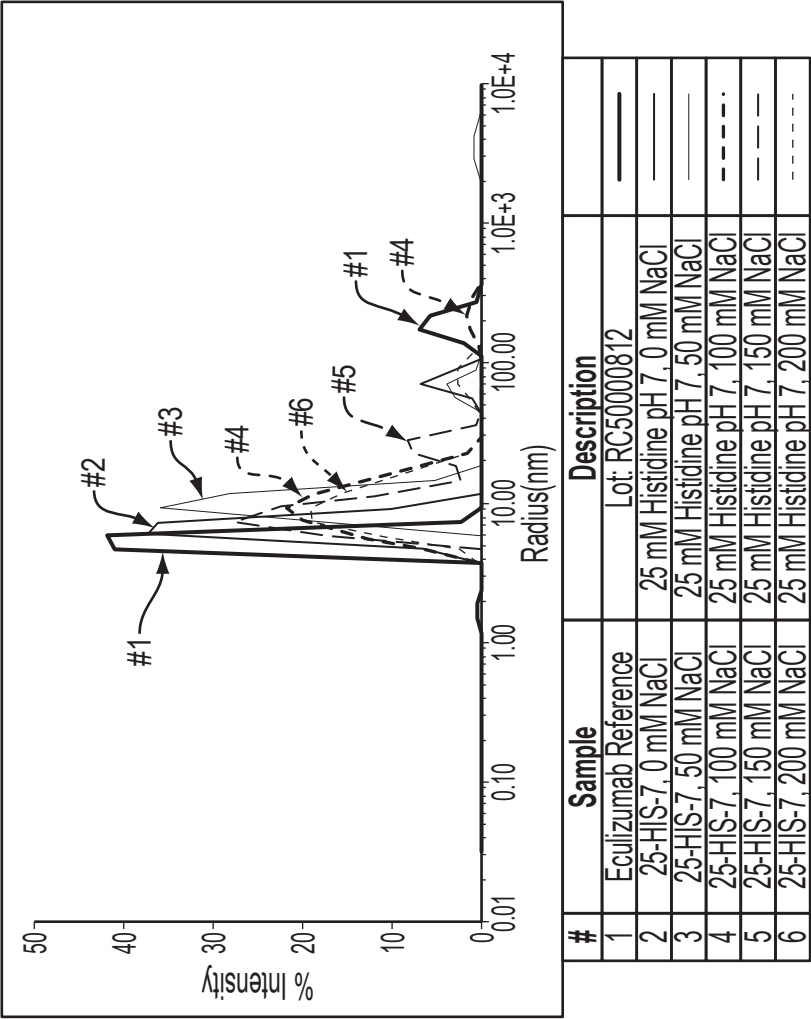
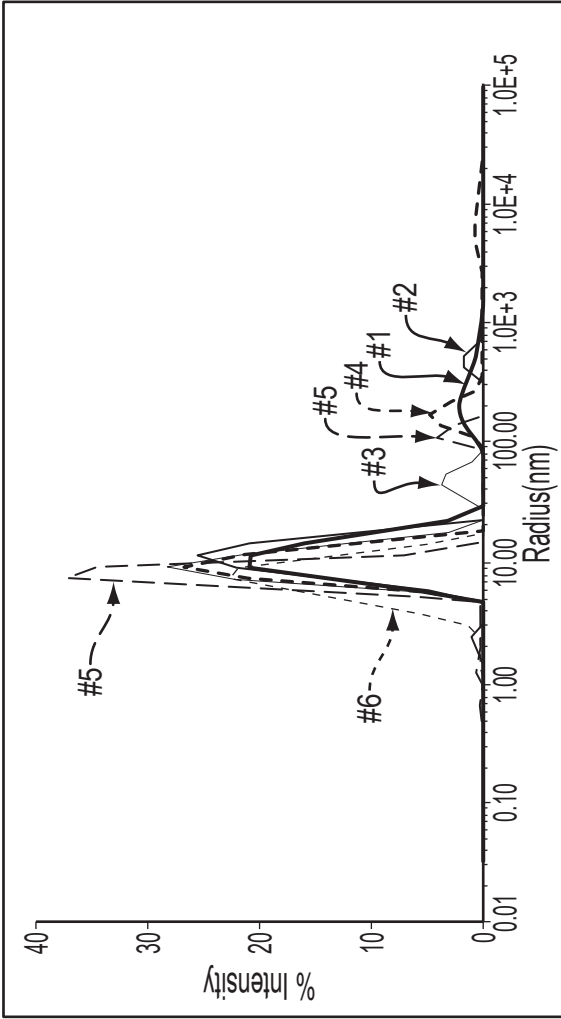


FIG. 1

Dynamic Light Scattering, L-Arginine Titration of Buffer
Exchanged ALXN1210 at 50 mg/mL



#	Sample	Description	
1	1210-SPPD-14-023, 0 mM L-Arginine	10 mM Sodium Phosphate, 150 mM NaCl, pH 7, 50 mg/mL, 0 mM L-Arginine	—
2	1210-SPPD-14-023, 1 mM L-Arginine	10 mM Sodium Phosphate, 150 mM NaCl, pH 7, 50 mg/mL, 1 mM L-Arginine	—
3	1210-SPPD-14-023, 2 mM L-Arginine	10 mM Sodium Phosphate, 150 mM NaCl, pH 7, 50 mg/mL, 2 mM L-Arginine	—
4	1210-SPPD-14-023, 5 mM L-Arginine	10 mM Sodium Phosphate, 150 mM NaCl, pH 7, 50 mg/mL, 5 mM L-Arginine	----
5	1210-SPPD-14-023, 10 mM L-Arginine	10 mM Sodium Phosphate, 150 mM NaCl, pH 7, 50 mg/mL, 10 mM L-Arginine	----
6	1210-SPPD-14-023, 25 mM L-Arginine	10 mM Sodium Phosphate, 150 mM NaCl, pH 7, 50 mg/mL, 25 mM L-Arginine	----

FIG. 2

Dynamic Light Scattering, Salt Titration of
Phosphate Buffer Exchanged ALXN1210 at 50 mg/mL

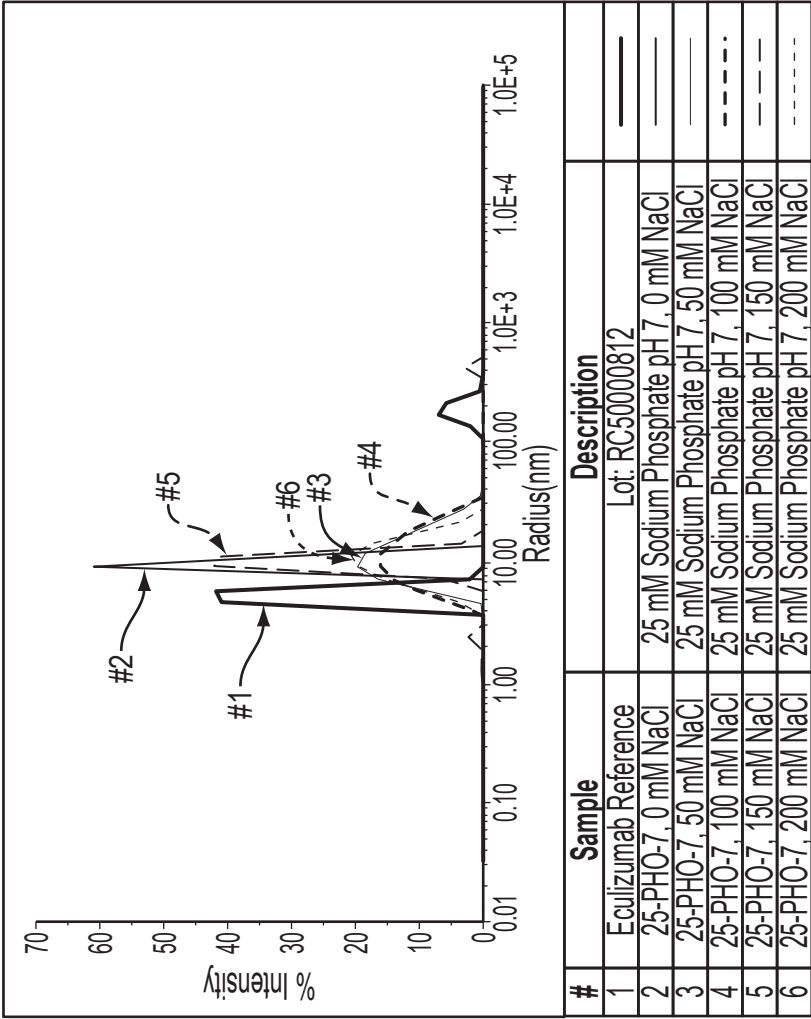


FIG. 3

Differential Scanning Fluorescence Buffer Exchanged ALXN1210 at 50 mg/mL

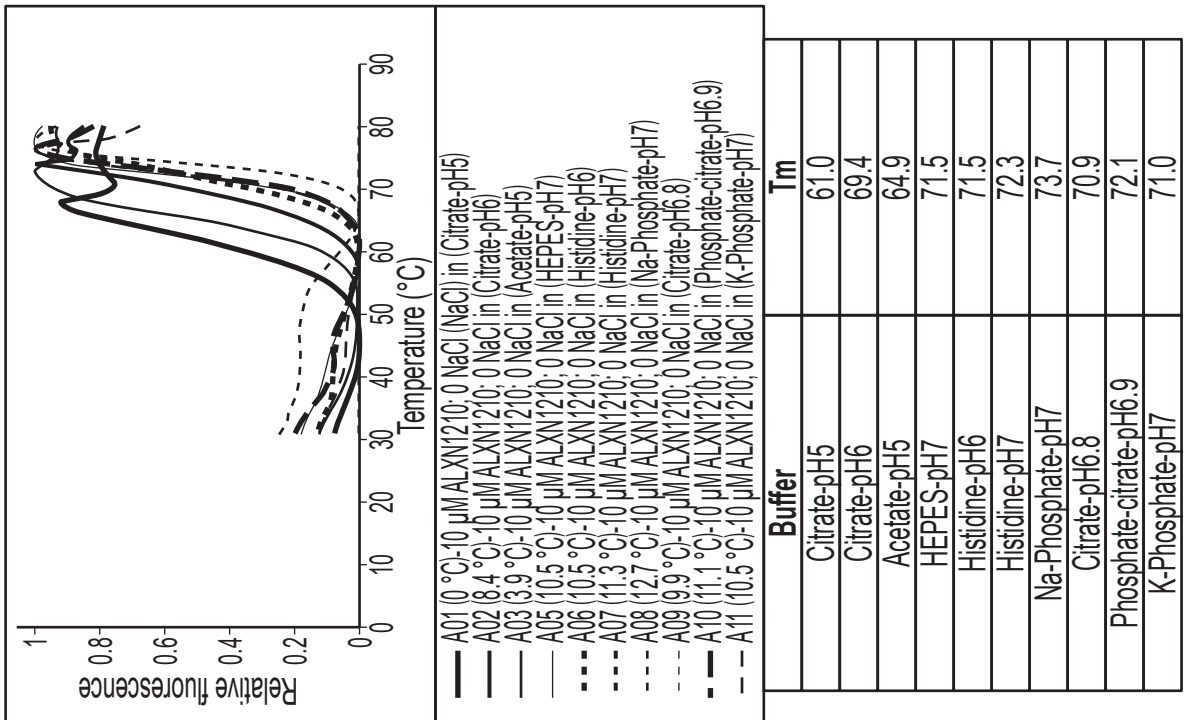


FIG. 4

Dynamic Light Scattering, ALXN1210 at 10 mg/mL and 114 mg/mL with no L-Arginine, and 114 mg/mL with addition of L-Arginine

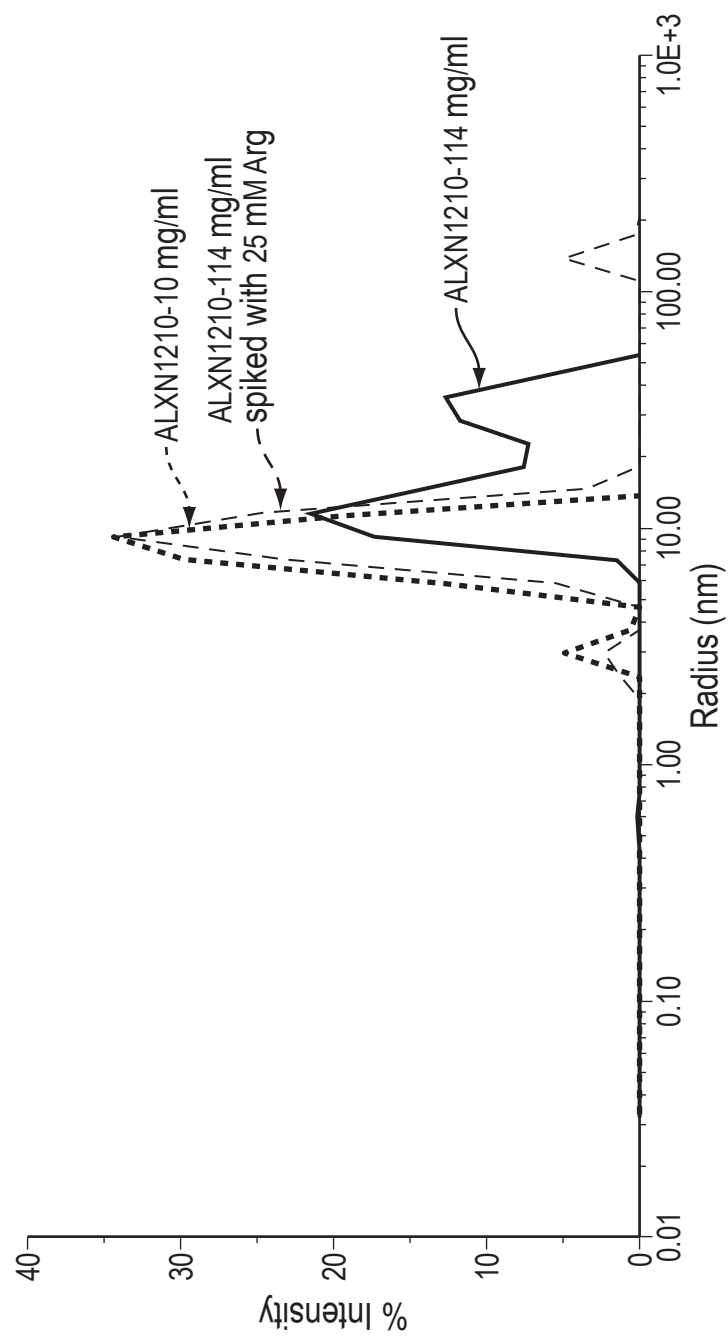


FIG. 5

Short Term Stability Study Results for ALXN1210 T=0 through T=2 Weeks at 2-8°C

2-8 °C		T=0					1 Week				2 Weeks				
Sample ID	Sample Description	Appearance	Osmolality (mOsm/kg)	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	pH	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Slightly opalescent, practically free from particles	299	58.4	98.9	pl range 6.02-6.53	Slightly opalescent, practically free from particles	6.99	58.0	98.9	pl range 6.01-6.51	Slightly opalescent, practically free from particles	58.6	98.8	pl range 6.02-6.53
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol		338	47.2	98.9	pl range 6.01-6.53		7.02	46.6	98.9	pl range 6.01-6.52		46.8	98.8	pl range 6.02-6.53
1210-AS-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose		301	73.2	98.2	pl range 6.02-6.53		7.76	74.9	98.1	pl range 5.91-6.52		75.8	98.0	pl range 6.01-6.52
1210-AS-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol		339	59.3	98.2	pl range 6.01-6.53		7.78	60.8	98.2	pl range 6.01-6.53		61.5	98.0	pl range 6.01-6.53
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose	Slightly opalescent, practically free from particles	349	93.2	99.2	pl range 6.02-6.53	Slightly opalescent, practically free from particles	8.89	92.9	99.2	pl range 6.03-6.54		95.0	99.1	pl range 6.00-6.52
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol		378	75.2	99.3	pl range 6.01-6.53		9.09	75.3	99.2	pl range 6.02-6.53		75.5	99.2	pl range 6.01-6.51

FIG. 6

Short Term Stability Study Results for ALXN1210 T=3 Weeks through T=2 Months at 2-8°C

2-8 °C		3 Weeks				1 Month				1.5 Months				2 Months				
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC %	Monomer	ICE	Appearance	Concentration (mg/mL)	SEC %	Monomer	ICE	Appearance	Osmolality (mOsm)	pH	Concentration (mg/mL)	SEC %	Monomer	ICE
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Slightly opalescent, practically free from particles	58.7	98.7	pI range 6.02-6.52	pI range 6.02-6.53		58.9	98.7	pI range 6.02-6.52	pI range 6.02-6.61	Slightly opalescent, light particles	295	6.74	58.2	98.4	pI range 6.02-6.52	
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol		47.3	98.7	pI range 6.00-6.52	pI range 6.02-6.52		51.7	98.7	pI range 6.02-6.52	pI range 6.01-6.58	Slightly opalescent, light particles	336	6.58	46.8	98.3	pI range 6.03-6.52	
1210-AS-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose		76.7	97.9	pI range 6.02-6.52	pI range 6.02-6.52	Slightly opalescent, practically free from particles	75.4	97.8	pI range 6.02-6.52	pI range 6.01-6.52	Slightly opalescent, light particles	311	7.22	72.5	97.3	pI range 6.03-6.52	
1210-AS-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol		62.1	97.9	pI range 6.01-6.52	pI range 6.02-6.52		62.0	97.8	pI range 6.02-6.52	pI range 6.01-6.52	Slightly opalescent, practically free from particles	333	7.54	59.5	97.2	pI range 6.02-6.52	
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose	Slightly opalescent, practically free from particles	94.2	99.1	pI range 6.01-6.51	pI range 6.02-6.52		93.3	99.1	pI range 6.02-6.52	pI range 6.01-6.52	Slightly opalescent, practically free from particles	348	8.81	94.2	98.9	pI range 6.02-6.52	
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol		76.1	99.1	pI range 6.01-6.52	pI range 6.02-6.52		75.9	99.1	pI range 6.02-6.52	pI range 6.01-6.52	Slightly opalescent, practically free from particles	370	9.01	76.0	99.0	pI range 6.02-6.52	

FIG. 7

Short Term Stability Study Results for ALXN1210 T=0 through T=3 Weeks at 23-27°C

23-27 °C		1 Week				2 Weeks				3 Weeks			
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC %	pI range	Appearance	Concentration (mg/mL)	SEC %	pI range	Appearance	Concentration (mg/mL)	SEC %	pI range
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Opalescent, light particulates	58.5	98.8	pI range 6.02-6.53	Opalescent, very cloudy, light particulates	59.1	98.8	pI range 6.02-6.52	Opalescent, very cloudy, light particulates	59.3	99.0	pI range 6.02-6.52
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol	Opalescent, light particulates	47.0	98.8	pI range 6.02-6.53	Opalescent, light particulates	48.1	98.6	pI range 6.01-6.52	Opalescent, light particulates	49.4	98.4	pI range 6.02-6.52
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose	Slightly opalescent, practically free from particles	95.3	99.1	pI range 6.01-6.52	Slightly opalescent, practically free from particles	94.5	98.7	pI range 5.91-6.53	Slightly opalescent, practically free from particles	93.8	98.5	pI range 5.92-6.37
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol	Slightly opalescent, practically free from particles	75.6	99.2	pI range 5.92-6.53	Slightly opalescent, practically free from particles	76.2	98.7	pI range 5.92-6.52	Slightly opalescent, practically free from particles	75.0	98.7	pI range 5.92-6.38

FIG. 8

Short Term Stability Study Results for ALXN1210 T=1 Month through T=2 Months at 23-27°C

23-27 °C		1 Month			1.5 Months			2 Months							
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Osmolality (mOsm/kg)	pH	Concentration (mg/mL)	SEC % Monomer	ICE
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Opalescent, very cloudy, heavy particulates	59.7	99.0	pl range 6.01-6.52	Opalescent, very cloudy, heavy particulates	59.6	92.7	pl range 6.12-6.62	Opalescent, very cloudy, light particulates	531	4.01	59.2	79.6	pl range 6.13-6.68
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol	Opalescent, light particulates	51.2	98.1	pl range 6.04-6.53	Opalescent, light particulates	53.3	97.5	pl range 6.01-6.52	Opalescent, light particulates	379	7.07	53.8	95.7	pl range 6.02-6.52
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose	Opalescent, light particulates	94.7	98.2	pl range 5.92-6.37	Opalescent, light particulates	93.3	98.1	pl range 5.85-6.52	Opalescent, light particulates	432	8.21	94.8	97.9	pl range 5.85-6.38
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol	Slightly opalescent, practically free from particles	75.9	98.3	pl range 5.85-6.38	Slightly opalescent, practically free from particles	75.6	98.1	pl range 5.85-6.38	Slightly opalescent, practically free from particles	371	8.97	76.2	97.6	pl range 5.79-6.37

FIG. 9

Short Term Stability Study Results for ALXN1210 T=1 Week through T=3 Weeks at 37°C

Sample ID	Sample Description	1 Week				2 Weeks				3 Weeks			
		Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Opalescent, light particulates	66.2	98.7	pl range 6.01-6.52	Opalescent, light particulates	64.3	98.7	pl range 6.01-6.52	Opalescent, light particulates	64.4	97.3	pl range 6.02-6.51
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol	Opalescent, light particulates	48.9	97.5	pl range 6.02-6.52	Opalescent, light particulates	59.1	95.3	pl range 6.02-6.64	Opalescent, moderate particulates	71.5	94.7	pl range 6.02-6.62
1210-AS-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Opalescent, light particulates	78.7	96.5	pl range 6.02-6.53	Opalescent, very cloudy, light particulates	78.5	95.0	pl range 5.93-6.63	Opalescent, very cloudy, light particulates	76.7	90.9	pl range 5.94-6.61
1210-AS-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol	Opalescent, light particulates	67.6	97.7	pl range 5.92-6.52	Opalescent, light particulates	69.4	97.2	pl range 5.92-6.37	Opalescent, light particulates	69.6	97.0	pl range 5.88-6.37
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose	Slightly opalescent, practically free from particles	93.6	97.1	pl range 5.91-6.53	Slightly opalescent, practically free from particles	93.4	95.0	pl range 5.76-6.37	Slightly opalescent, practically free from particles	94.4	92.8	pl range 5.73-6.24
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol	Slightly opalescent, practically free from particles	74.7	97.0	pl range 5.92-6.52	Slightly opalescent, practically free from particles	75.8	94.5	pl range 5.77-6.38	Slightly opalescent, practically free from particles	76.3	92.7	pl range 5.78-6.24

FIG. 10

Short Term Stability Study Results for ALXN1210 T=1 Month through T=2 Months at 37°C

37 °C		1 Month			1.5 Months			2 Months							
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Osmolality (mOsm/kg)	pH	Concentration (mg/mL)	SEC % Monomer	ICE
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Opalescent, moderate particulates	64.9	94.1	pl range 6.05-6.50	Opalescent, moderate particulates	64.3	78.8	pl range 6.12-6.36	Opalescent, yellow tint, moderate particulates	558	3.96	64.5	46.1	No result, Sample Degraded
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol	Opalescent, moderate particulates	78.9	93.7	pl range 6.02-6.62	Opalescent, moderate particulates	82.4	92.3	pl range 5.93-6.62	Opalescent, yellow tint, moderate particulates	393	7.01	78.1	91.2	pl range 5.94-6.62
1210-AS-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Opalescent, very cloudy, light particulates	78.8	82.4	pl range 6.01-6.23	Opalescent, very cloudy, light particulates	75.7	54.8	No result, Sample Degraded	Opalescent, yellow tint, very cloudy, light particulates	546	4.08	77.2	25.1	No result, Sample Degraded
1210-AS-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol	Opalescent, light particulates	72.3	94.9	pl range 5.93-6.37	Opalescent, light particulates	72.1	96.3	pl range 5.85-6.62	Opalescent, yellow tint, light particulates	400	7.21	54.8	91.1	
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose	Slightly opalescent, practically free from particles	95.3	91.0	pl range 5.79-6.25	Slightly opalescent, practically free from particles	94.8	87.6	pl range 6.00-6.52	Slightly opalescent, light particles	388	7.79	93.7	84.9	
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol	Slightly opalescent, practically free from particles	76.7	90.8	pl range 5.78-6.26	Slightly opalescent, practically free from particles	76.6	87.5	pl range 6.00-6.51	Slightly opalescent, practically free from particles	376	8.90	76.3	83.1	

FIG. 11

Short Term Stability SEC, % Monomer for ALXN1210
T=0 through T=2 Months 2-8°C

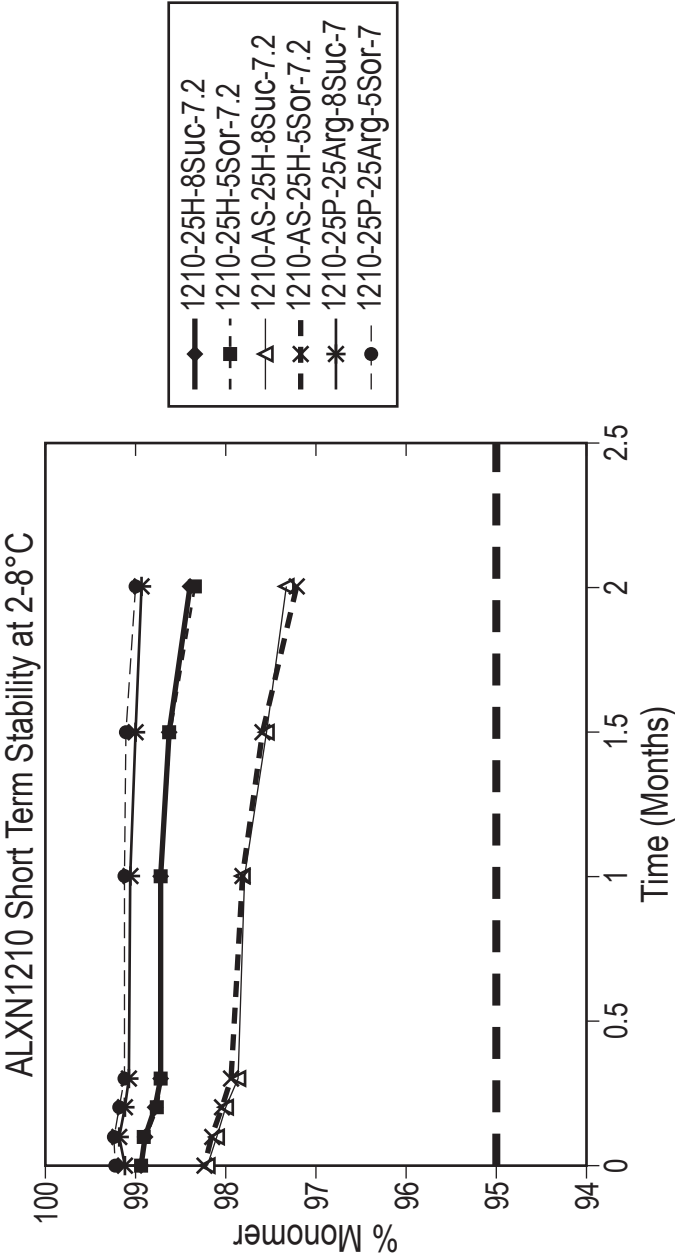


FIG. 12

Short Term Stability SEC, % Monomer for ALXN1210
T=0 through T=2 Months 23-27°C

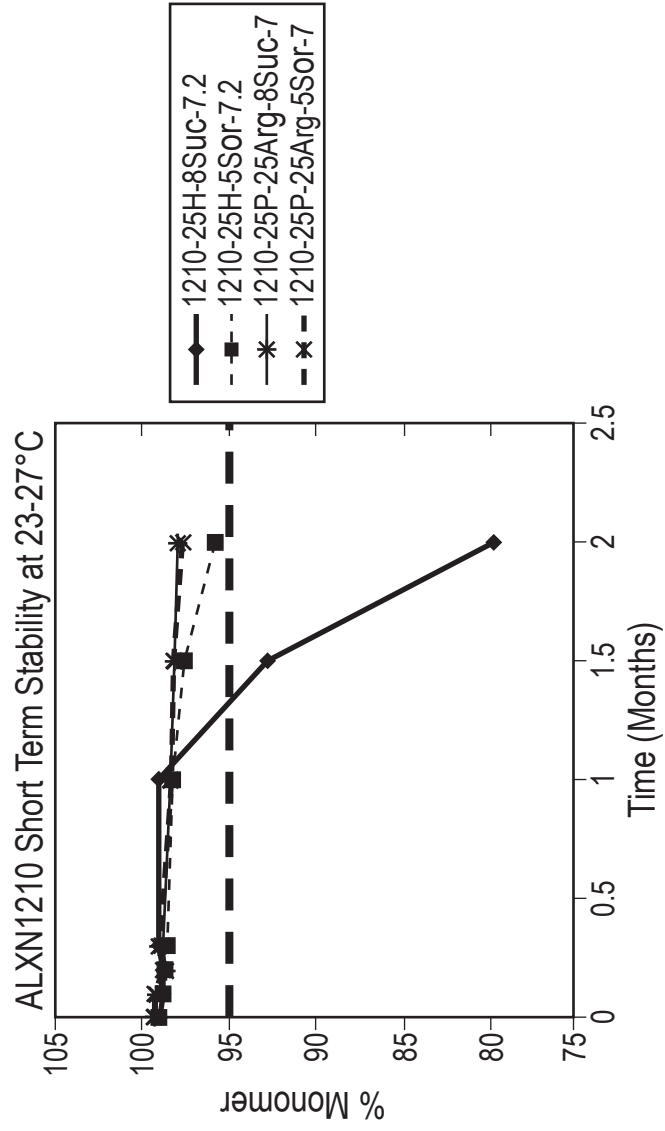


FIG. 13

Short Term Stability SEC, % Monomer for ALXN1210
T=0 through T=2 Months 37°C

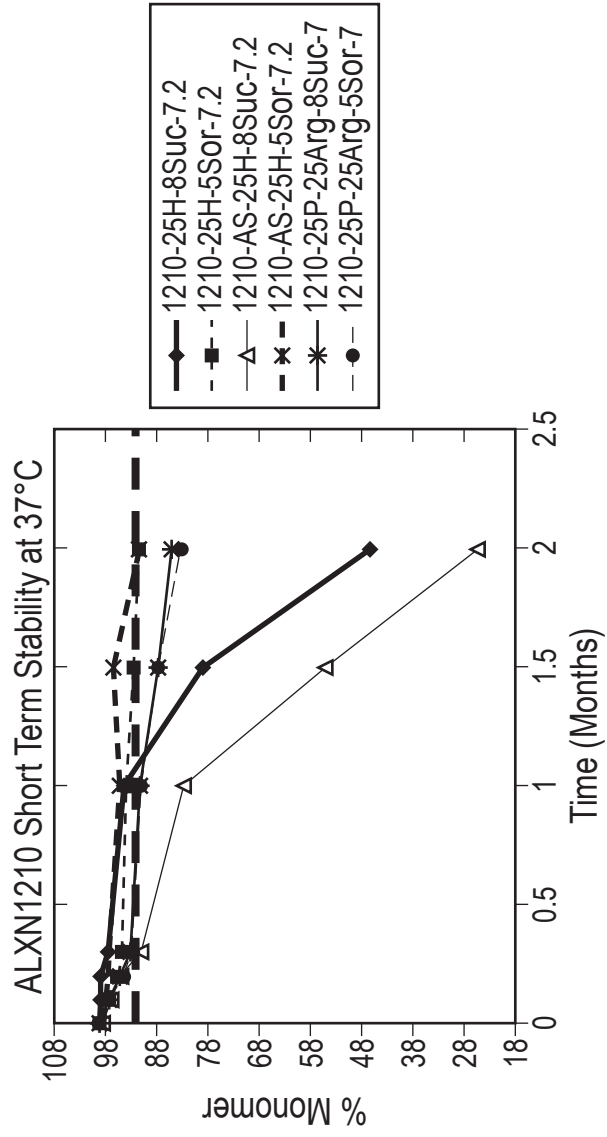


FIG. 14

Short Term Stability Dynamic Light Scattering ALXN1210
Histidine Samples T=0

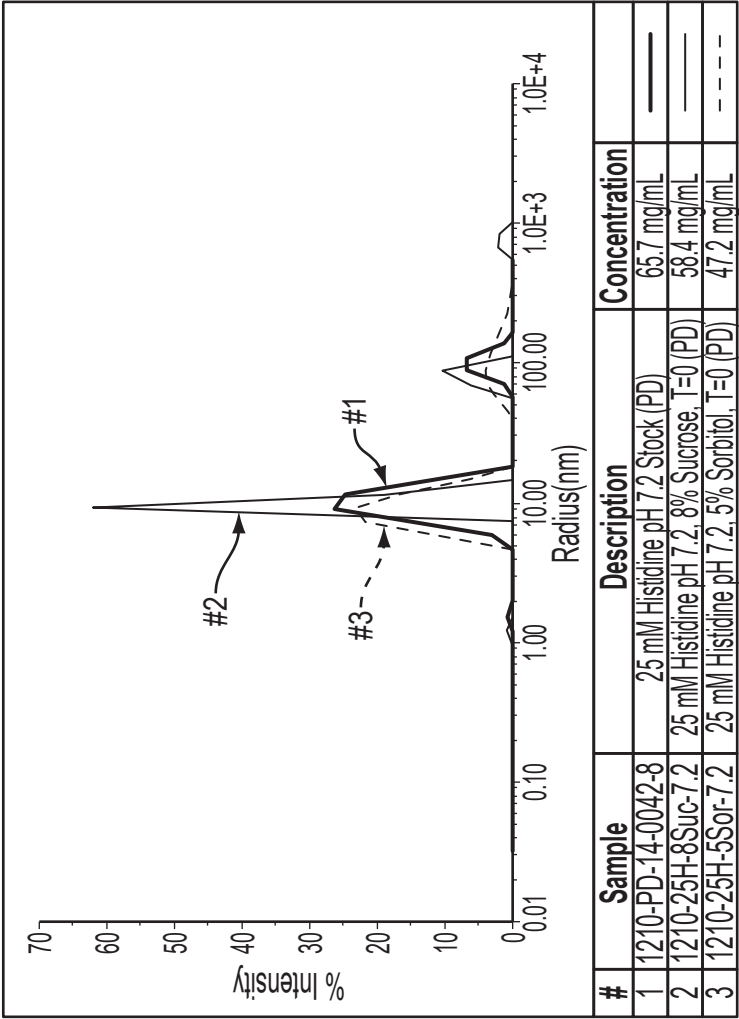


FIG. 15

Short Term Stability Dynamic Light Scattering ALXN1210
Histidine AS Samples T=0

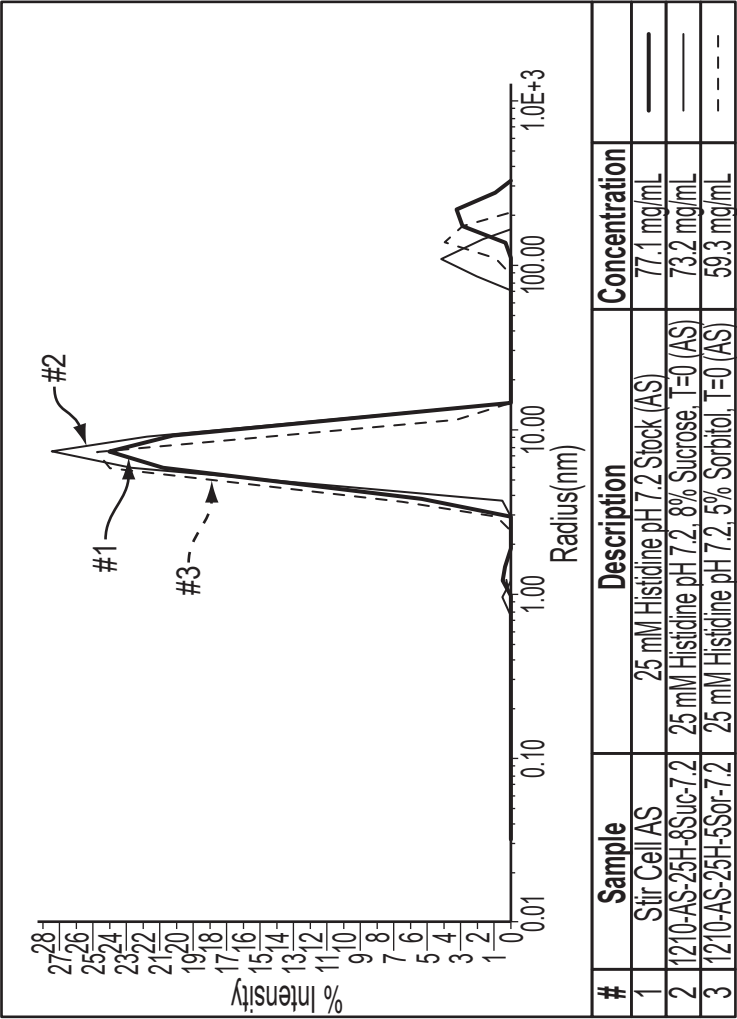


FIG. 16

Short Term Stability Dynamic Light Scattering ALXN1210
Phosphate Samples T=0

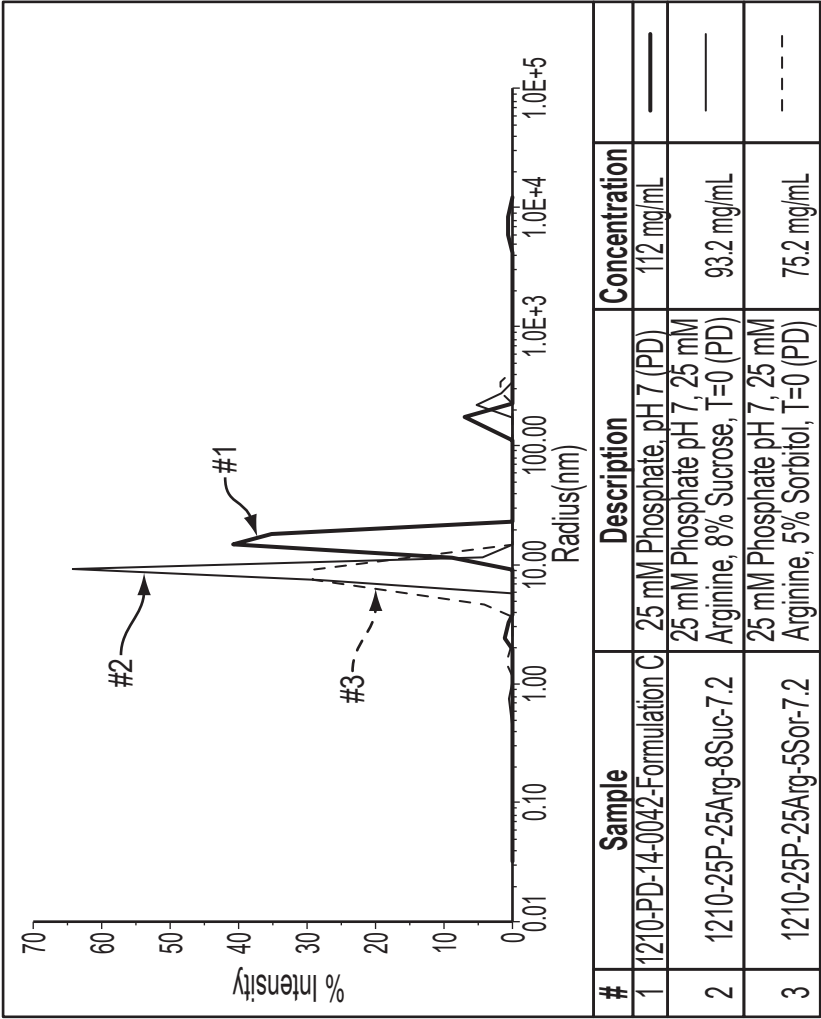


FIG. 17

Short Term Stability Dynamic Light Scattering ALXN1210
Phosphate Samples T=2 Months 2-8°C

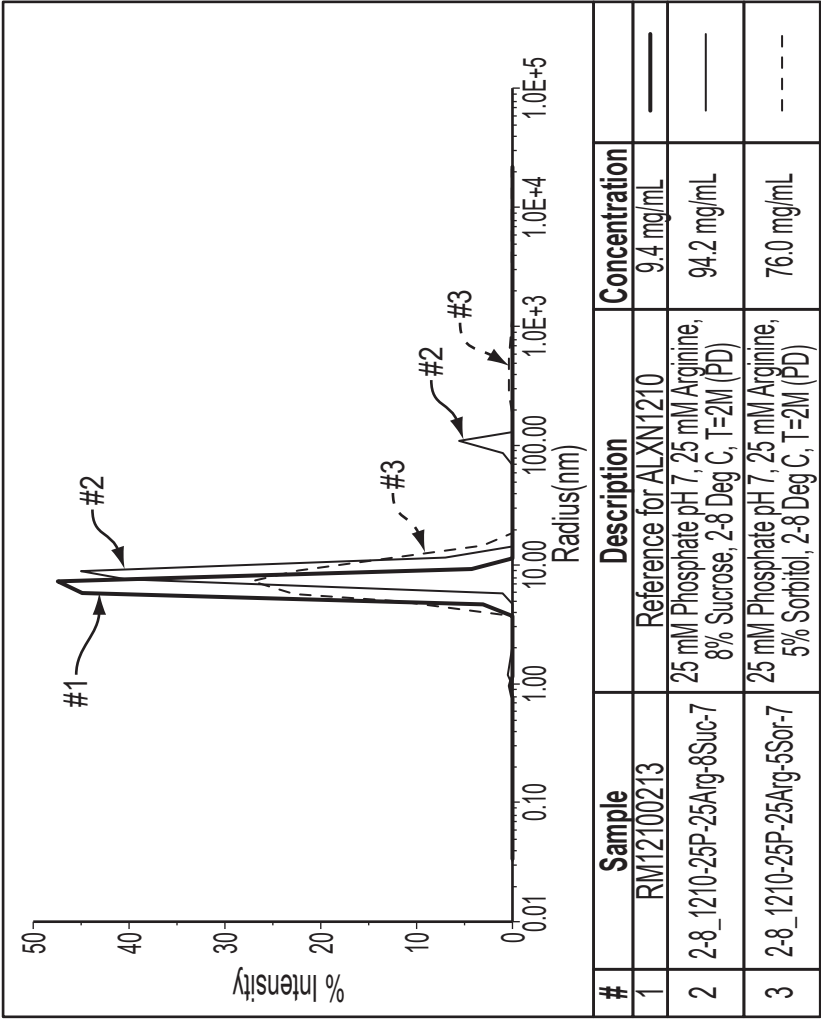


FIG. 18

Short Term Stability Study Results for ALXN1210
Freeze Thaw T=0 through Cycle 2 at T=1M -20°C

-20 °C		T=0				FT1				FT2		
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	pI range	Appearance	Concentration (mg/mL)	SEC % Monomer	pI range	Appearance	Concentration (mg/mL)	SEC % Monomer
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Slightly opalescent, practically free from particles	58.4	98.9	pI range 6.02-6.53	Slightly opalescent, practically free from particles	58.0	98.7	pI range 6.02-6.60	Slightly opalescent, practically free from particles	58.8	98.8
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol		47.2	98.9	pI range 6.01-6.53		46.4	98.8	pI range 6.00-6.52		46.5	98.8
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose		93.2	99.1	pI range 6.02-6.53		94.1	99.1	pI range 6.01-6.52		93.8	99.2
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol		75.2	99.2	pI range 6.01-6.53		75.2	99.2	pI range 6.01-6.52		74.5	99.2

FIG. 19

Short Term Stability Study Results for ALXN1210
Freeze Thaw Cycle 3 through Cycle 5 at T=-20°C

-20 °C		FT3				FT4			FT5			
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE
1210-25H-8Suc-7.2	ALXN1210, 25 mM Histidine pH 7.2, 8% Sucrose	Slightly opalescent, practically free from particles	57.9	98.8	pl range 6.02-6.52	Slightly opalescent, practically free from particles	58.3	98.7	Slightly opalescent, practically free from particles	56.9	98.8	pl range 6.02-6.52
1210-25H-5Sor-7.2	ALXN1210, 25 mM Histidine pH 7.2, 5% Sorbitol		46.7	98.8	pl range 6.03-6.61		46.5	98.8		46.2	98.7	pl range 6.02-6.52
1210-25P-25Arg-8Suc-7	ALXN1210, 25 mM Phosphate pH 7, 8% Sucrose		94.5	99.2	pl range 6.01-6.52		92.6	99.2		91.9	99.2	pl range 6.02-6.52
1210-25P-25Arg-5Sor-7	ALXN1210, 25 mM Phosphate pH 7, 5% Sorbitol		75.1	99.2	pl range 6.01-6.59		74.5	99.2		74.7	99.2	pl range 6.02-6.52

FIG. 20

Short Term Stability SEC, % Monomer for ALXN1210
Freeze Thaw at T=1 Month -20°C

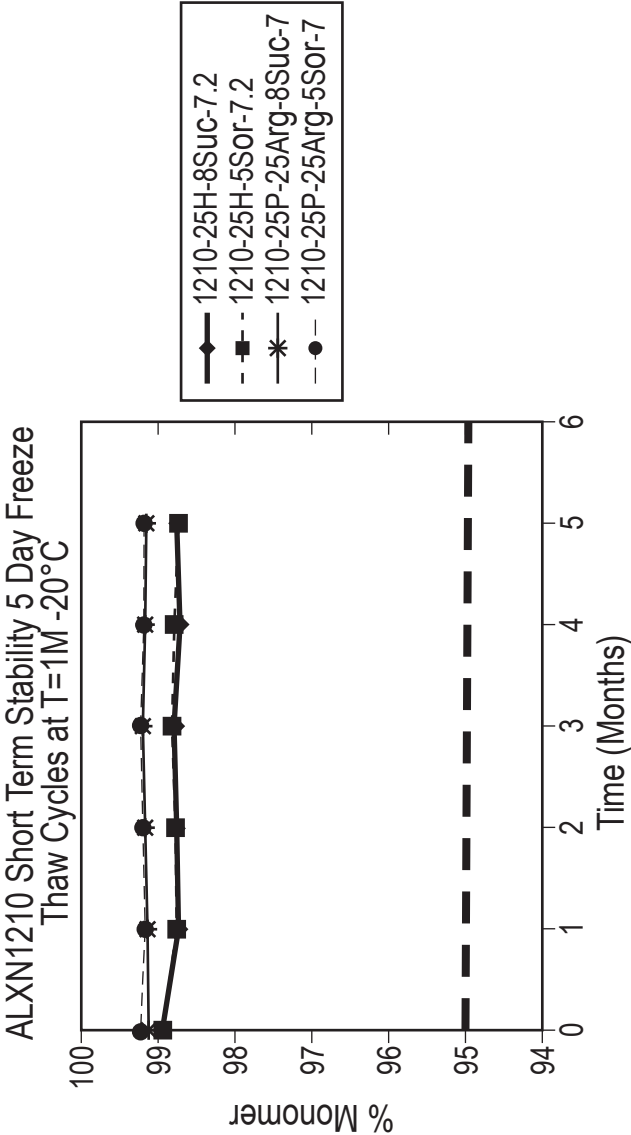


FIG. 21

Prototype Stability Study Results for ALXN1210
T=0 through T=2 Months at 2-8°C (SPAS-14-007)

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2-8 °C		T=0										1M		2M		
Sample ID	Sample Description	Appearance	Osmolality (mOsm/kg)	pH	Concentration (mg/mL)	SEC % Monomer	Viscosity (mPas)	Density (g/cm3)	Potency	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	SEC % Monomer
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine	Slightly opalescent, practically free from particles	287	7.45	73.3	98.7	3.408	1.045	94% activity relative to reference	98.1% IgG as main band	100% as Heavy & Light	pl range 6.03-6.52	Slightly opalescent, practically free from particles	74.9	98.5	98.4
1210-75-25P-7.0-3So-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine		296	7.50	71.2	98.8	3.156	1.036	107% activity relative to reference	98.0% IgG as main band	100% as Heavy & Light	pl 6.22, pl range 6.02-6.52		72.2	98.6	98.4
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS		275	7.44	96.4	98.4			91% activity relative to reference	98.1% IgG as main band	100% as Heavy & Light	pl range 6.01-6.52		99.2	98.0	97.9
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS		271	7.37	100.4	98.4	6.497	1.040	96% activity relative to reference	98.1% IgG as main band	100% as Heavy & Light	pl range 6.03-6.52		99.4	98.1	98.3
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP		275	7.42	96.0	98.4			111% activity relative to reference	98.0% IgG as main band	100% as Heavy & Light	pl range 6.03-6.52		96.3	97.9	
1210-100-25P-7.0-3So-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP		268	7.36	99.7	98.4	7.237	1.041	108% activity relative to reference	98.1% IgG as main band	100% as Heavy & Light	pl range 6.02-6.52		101.0	98.1	

FIG. 22

Prototype Stability Study Results for ALXN1210
T=3 Months through T=6 Months at 2-8°C (SPAS-14-007)

2-8 °C		3M						6M							
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine	Slightly opalescent, practically free from particles	79.9	98.48		97.5% IgG as main band	100% as Heavy & Light	pl range 6.00-6.51	opalescent, practically free from particles	80.0	98.1	102	96.8% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-75-25P-7.0-3So-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine	Slightly opalescent, practically free from particles	72.8	98.7	99% Activity relative to reference	97.5% IgG as main band	100% as Heavy & Light	pl range 6.01-6.52	opalescent, practically free from particles	72.9	98.5	101	97.5% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	101.7	98.14		97.6% IgG as main band	100% as Heavy & Light	pl range 6.00-6.51	opalescent, practically free from particles	104.6	97.6	101	96.7% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	102.1	98.16	96% Activity relative to reference	97.6% IgG as main band	100% as Heavy & Light	pl range 6.02-6.51	opalescent, practically free from particles	101.6	97.9	99	97.6% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP	Slightly opalescent, practically free from particles	98.9	97.81		97.6% IgG as main band	100% as Heavy & Light	pl range 6.02-6.51	opalescent, practically free from particles	104.6	97.8		96.7% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-3So-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP	Slightly opalescent, practically free from particles	100.2	98.21	95% Activity relative to reference	97.5% IgG as main band	100% as Heavy & Light	pl range 6.01-6.51	opalescent, practically free from particles	101.6	97.9		96.4% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5

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FIG. 23

Prototype Stability Study Results for ALXN1210
T=9 Months through T=12 Months at 2-8°C (SPAS-14-007)

6M		9M					12M									
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	LOC Non-reduced	LOC Reduced	ICE	Appearance	pH	Osmolality (mOsm/kg)	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine	opalescent, light particles	74.0	98.6	97.3% IgG as main band	100.0% as Heavy & Light	pl range 6.0-6.5	very opalescent, light particles	7.58	294	75.2	98.2	86% activity relative to reference	98.3% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-75-25P-7.0-3So-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine	opalescent, practically free from particles	74.7	98.4	97.3% IgG as main band	100.0% as Heavy & Light	pl range 6.0-6.5	opalescent, practically free from particles	7.59	310	76.0	97.8	85% activity relative to reference	98.3% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	opalescent, practically free from particles	116.4	97.8	97.3% IgG as main band	100.0% as Heavy & Light	pl range 6.0-6.5	opalescent, practically free from particles	7.47		122.5	97.3	85% activity relative to reference	98.3% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	opalescent, practically light particles	105.8	98.0	97.3% IgG as main band	100.0% as Heavy & Light	pl range 6.0-6.5	opalescent, practically light particles	7.45	278	102.0	97.5	76% activity relative to reference	98.2% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP	opalescent, practically free from particles	104.6	98.0	97.9% IgG as main band	100.0% as Heavy & Light	pl range 6.0-6.5	opalescent, practically free from particles	7.51	296	100.8	97.4	78% activity relative to reference	98.3% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-3So-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP	opalescent, practically free from particles	104.7	97.8	98.0% IgG as main band	100.0% as Heavy & Light	pl range 6.0-6.5	opalescent, practically free from particles	7.46	274	103.4	97.5	92% activity relative to reference	98.2% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5

FIG. 24

Prototype Stability Study Results for ALXN1210
T=1 Month through T=2 Months at 23-27°C (SPAS-14-007)

23-27 °C		1M						2M		
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE	pH	SEC % Monomer
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine	Slightly opalescent, practically free from particles	82.0	97.9	104% relative activity	96.8% IgG as main band	100% as Heavy & Light	pl range 6.02-6.51	7.41	96.6
1210-75-25P-7.0-3So-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine		74.0	97.3	92% relative activity	96.4% IgG as main band	100% as Heavy & Light	pl range 6.01-6.51	7.47	94.5
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS		102.2	97.4	110% relative activity	96.7% IgG as main band	100% as Heavy & Light	pl range 6.02-6.52	7.4	95.5
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS		102.7	97.0	90% relative activity	96.4% IgG as main band	100% as Heavy & Light	pl range 6.02-6.52	7.41	94.3
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP		97.3	97.6	99% relative activity	96.8% IgG as main band	100% as Heavy & Light	pl range 6.01-6.52	7.34	
1210-100-25P-7.0-3So-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP		98.6	97.2	94% relative activity	96.5% IgG as main band	100% as Heavy & Light	pl range 6.01-6.51	7.17	

FIG. 25

Prototype Stability Study Results for ALXN1210
T=3 Month through T=6 Months at 23-27°C (SPAS-14-007)

Sample ID	Sample Description	23-27 °C						3M						6M									
		Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	LOC	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	LOC	LOC Non-reduced	LOC Reduced	ICE
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine	Slightly opalescent, practically free from particles	127.9	96.1		94.8% IgG as main band	100% as Heavy & Light		pl range 5.92-6.51														
1210-75-25P-7.0-3S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine	Slightly opalescent, practically free from particles	78.2	93.4	88% Activity relative to reference	92.9% IgG as main band	100% as Heavy & Light		pl range 5.86-6.51	Opalescent, practically free from particles	85.6	87.2	87.9% IgG as main band	92.5% as Heavy & Light	pl range 5.8-6.4								
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	122.4	94.5		93.5% IgG as main band	100% as Heavy & Light		pl range 5.92-6.51	Opalescent, practically free from particles	180.9	87.9	87.6% IgG as main band	98.4% as Heavy & Light	pl range 5.9-6.4								
1210-100-25P-7.0-3S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	103.6	93.1	90% Activity relative to reference	93.3% IgG as main band	100% as Heavy & Light		pl range 5.93-6.51	Opalescent, practically free from particles	110.0	87	86.8% IgG as main band	94.0% as Heavy & Light	pl range 5.9-6.6								
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP	Slightly opalescent, light particles	100.7	96.3		95.2% IgG as main band	100% as Heavy & Light		pl range 5.93-6.51	Opalescent, light particles	104.3	95.8	91.8% IgG as main band	98.5% as Heavy & Light	pl range 5.9-6.6								
1210-100-25P-7.0-3S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP	Slightly opalescent, practically free from particles	100.0	93.8	96% Activity relative to reference	93.7% IgG as main band	100% as Heavy & Light		pl range 5.93-6.51	Opalescent, practically free from particles	101.0	88.4	88.3% IgG as main band	100.0% as Heavy & Light	pl range 5.9-6.5								

FIG. 26

Prototype Stability Study Results for ALXN1210
T=9 Month through T=12 Months at 23-27°C (SPAS-14-007)

23-27 °C		9M							12M						
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine														
1210-75-25P-7.0-3So-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine	Opalescent, slight yellowish color practically free from particles	93.3	81.1	61% Activity relative to reference	70.0% IgG as main band	87.9% as Heavy & Light	pl range 5.6-6.4	Opalescent, yellowish color practically free from particles	93.3	77.3	40% Activity relative to reference	67.7% IgG as main band	84.9% as Heavy & Light	pl range 5.5-6.6
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS														
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Opalescent, slight yellowish color practically free from particles	121.1	81.2	75% Activity relative to reference	76.7% IgG as main band	97.4% as Heavy & Light	pl range 5.7-6.4	Opalescent, yellowish color practically free from particles	122.2	75.0	49% Activity relative to reference	71.4% IgG as main band	87.3% as Heavy & Light	pl range 5.7-6.5
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP	Opalescent, slight yellowish color light particles	105.4	93.5	77% Activity relative to reference	88.5% IgG as main band	100% as Heavy & Light	pl range 5.7-6.4	Opalescent, dark yellowish color light particles	111.1	89.2	69% Activity relative to reference	85.6% IgG as main band	95.1% as Heavy & Light	pl range 5.5-6.5
1210-100-25P-7.0-3So-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP	Opalescent, slight yellowish color practically free from particles	103.4	83.2	75% Activity relative to reference	77.6% IgG as main band	94.0% as Heavy & Light	pl range 5.7 and 6.4	Opalescent, slight yellowish color practically free from particles	106.9	77.9	47% Activity relative to reference	73.5% IgG as main band	89.1% as Heavy & Light	pl range 5.6-6.5

FIG. 27

Prototype Stability Study Results for ALXN1210
T=2 Weeks through T=2 Months at 37°C (SPAS-14-007)

37 °C		T=2 WKS							1M						2M			
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC	Non-reduced LOC	Reduced LOC	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC	Non-reduced LOC	Reduced LOC	ICE	SEC % Monomer
1210-75-25P-7.0-5S-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine	Slightly opalescent, practically free from particles	85.2	93.0	85% Activity relative to reference	94.0% IgG as main band	96.5% as Heavy & Light	pl range 5.93-6.52	pl range 5.93-6.52		71.1	90.8	75% Activity relative to reference	89.6% IgG as main band	96.2% as Heavy & Light	pl range 5.92-6.51		
1210-75-25P-7.0-3So-25R	ALXN1210, 75 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine		74.8	92.2	81% Activity relative to reference	93.4% IgG as main band	98.3% as Heavy & Light	pl range 5.93-6.52	pl range 5.93-6.52			72.5	72% Activity relative to reference	78.2% IgG as main band	92.0% as Heavy & Light	pl range 5.93-6.37		63.4
1210-100-25P-7.0-5S-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, DP		120.1	93.1	88% Activity relative to reference	94.0% IgG as main band	98.8% as Heavy & Light	pl range 5.93-6.52	pl range 5.93-6.52		91.1	81.7	83% Activity relative to reference	88.6% IgG as main band	96.5% as Heavy & Light	pl range 5.91-6.51		73.2
1210-100-25P-7.0-3So-25R_DP	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, DP		102.7	92.0	81% Activity relative to reference	93.4% IgG as main band	98.9% as Heavy & Light	pl range 5.93-6.51	pl range 5.93-6.51		109.6	84.1	84% Activity relative to reference	86.3% IgG as main band	94.9% as Heavy & Light	pl range 5.04-6.37		52.0

FIG. 28

Prototype Stability Study Results for ALXN1210
T=1 Month through T=3 Months at -20 °C (SPAS-14-007)

-20 °C		1M						3M						
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	LOC Non-reduced	LOC Reduced	ICE
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	97.4	98.2	106% Activity relative to reference	97.6% IgG as main band	100.0% as Heavy & Light	pl range 6.02-6.52	Slightly opalescent, light particles	103.9	98.5	97.5% IgG as main band	100% as Heavy & Light	pl range 6.00-6.51
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS		99.5	98.2	118% Activity relative to reference	97.6% IgG as main band	100.0% as Heavy & Light	pl range 6.03-6.52	Slightly opalescent, light particles	101.5	98.6	97.5% IgG as main band	100% as Heavy & Light	pl range 6.02-6.51

FIG. 29

Prototype Stability Study Results for ALXN1210
T=6 Months through T=12 Months at -20°C (SPAS-14-007)

-20 °C		6M						12M						
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	LOC Non-reduced	LOC Reduced	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Opalescent, light particles	111.4	98.2	97.6% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5	Opalescent, light particles	99.9	98.3	95% Activity relative to reference	98.1% IgG as main band	% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS		101.9	98.3	97.5% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5	Opalescent, light particles	100.6	98.3	95% Activity relative to reference	98.2% IgG as main band	% as Heavy & Light	pl range 6.0-6.5

FIG. 30

Prototype Stability Study Results for ALXN1210
T=3 Months through T=6 Months at -80°C (SPAS-14-007)

Sample ID		Sample Description	-80 °C						3M						6M					
			Appearance	Concentration (mg/mL)	SEC %	LOC	Non-reduced	LOC	Reduced	ICE	Appearance	Concentration (mg/mL)	SEC %	LOC	Non-reduced	LOC	Reduced	ICE		
1210-100-25P-7.0-5S-25R_BDS		ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, light particles	100.6	98.5	97.5% IgG as main band	100% as Heavy & Light	pl range 6.01-6.51	Opalescent, light particles	99.1	99.1	97.5% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5						
1210-100-25P-7.0-3S-25R_BDS		ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Slightly opalescent, light particles	101.8	98.6	97.6% IgG as main band	100% as Heavy & Light	pl range 6.02-6.51	Opalescent, light particles	102.9	98.3	97.5% IgG as main band	100% as Heavy & Light	pl range 6.0-6.5						

FIG. 31

Prototype Stability Study Results for ALXN1210
T=12 Months at -80 °C (SPAS-14-007)

-80 °C		12M						
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Potency	LOC Non-reduced	LOC Reduced	ICE
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Opalescent, light particles	106.4	98.3	85% Activity relative to reference	98.1% IgG as main band	% as Heavy & Light	pl range 6.0-6.5
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Opalescent, light particles	103.3	98.3	83% Activity relative to reference	98.1% IgG as main band	% as Heavy & Light	pl range 6.0-6.5

FIG. 32

Prototype Stability SEC, % Monomer for ALXN1210
T=0 through T=12 Months 2-8°C

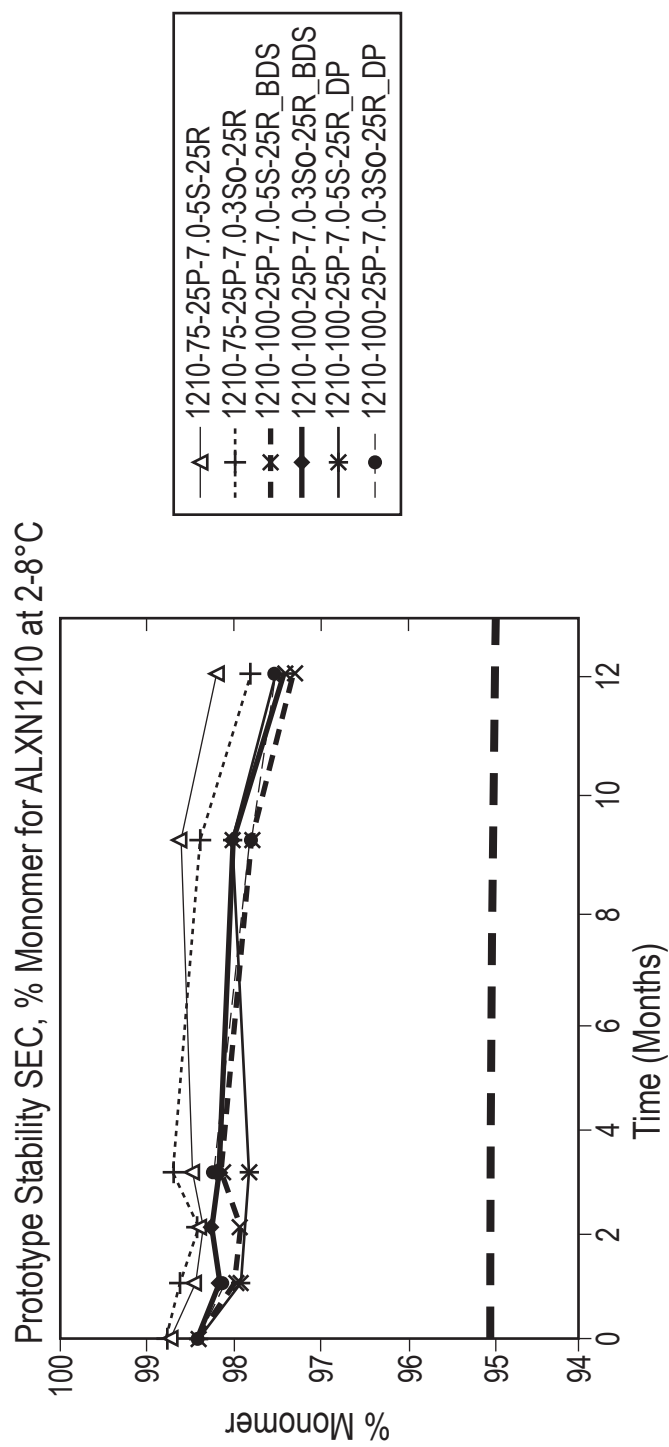


FIG. 33

Prototype Stability SEC, % Monomer for ALXN1210
T=0 through T=12 Months 23-27°C

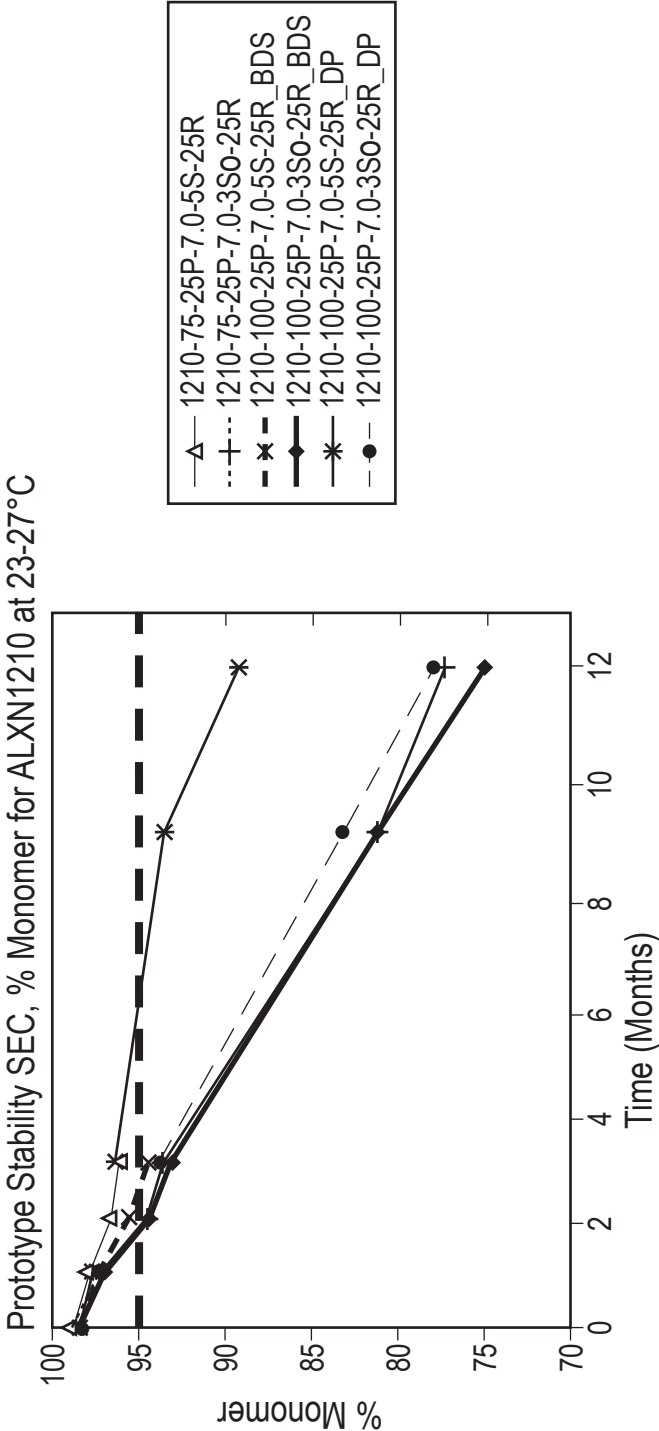


FIG. 34

Prototype Stability SEC, % Monomer for ALXN1210
T=0 through T=12 Months 37°C

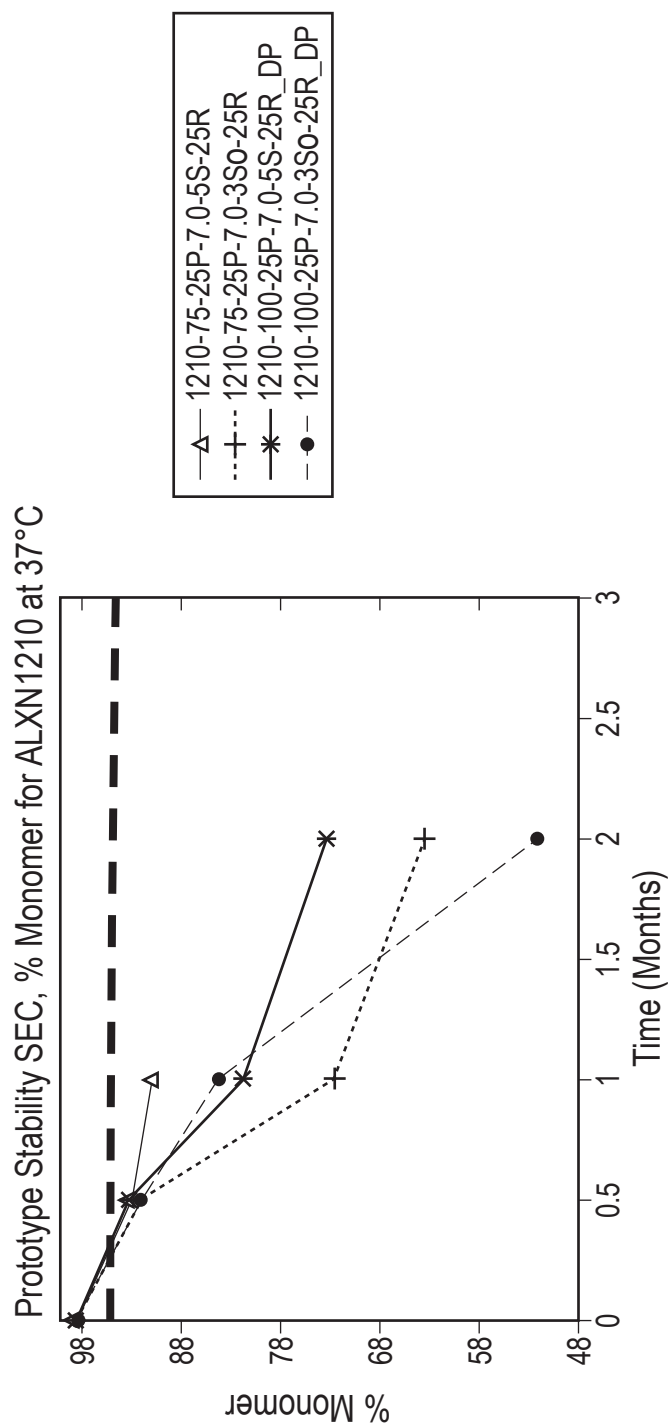


FIG. 35

Prototype Stability SEC, % Monomer for ALXN1210
T=0 through T=12 Months -20°C

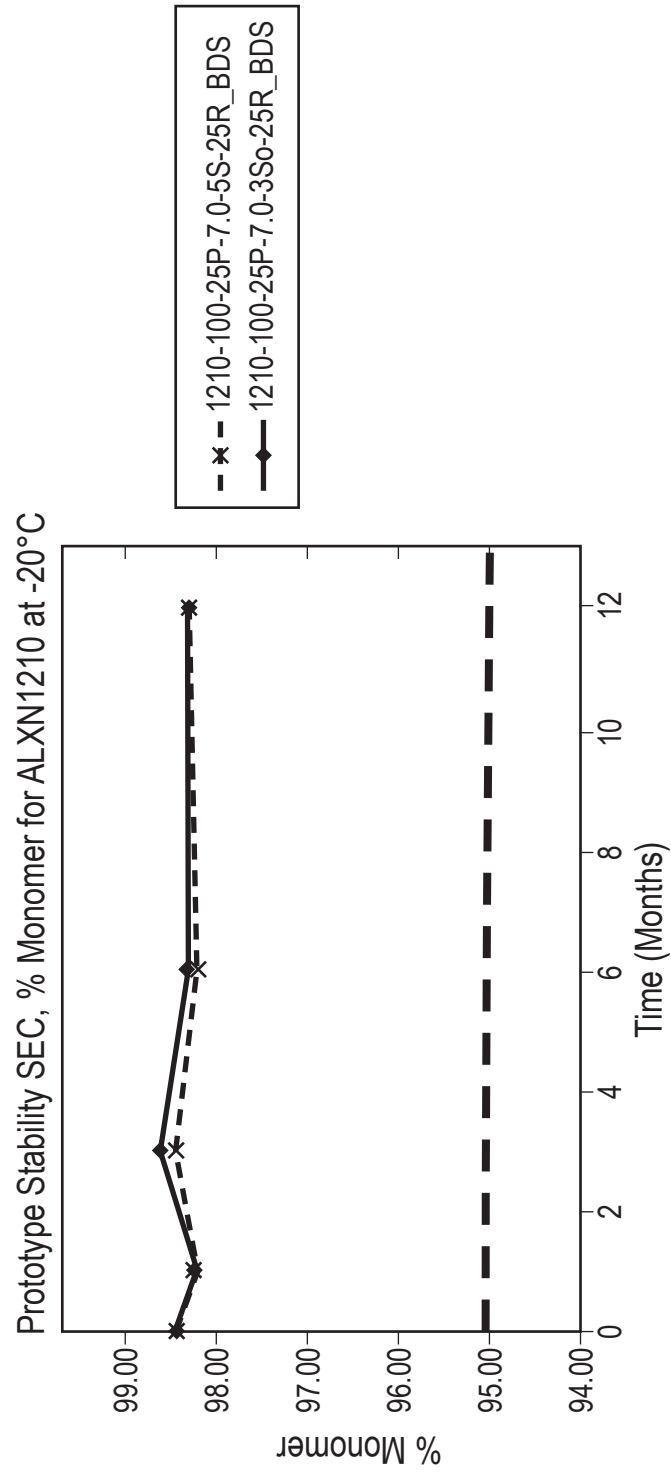


FIG. 36

Prototype Stability SEC, % Monomer for ALXN1210
T=0 through T=12 Months -80°C

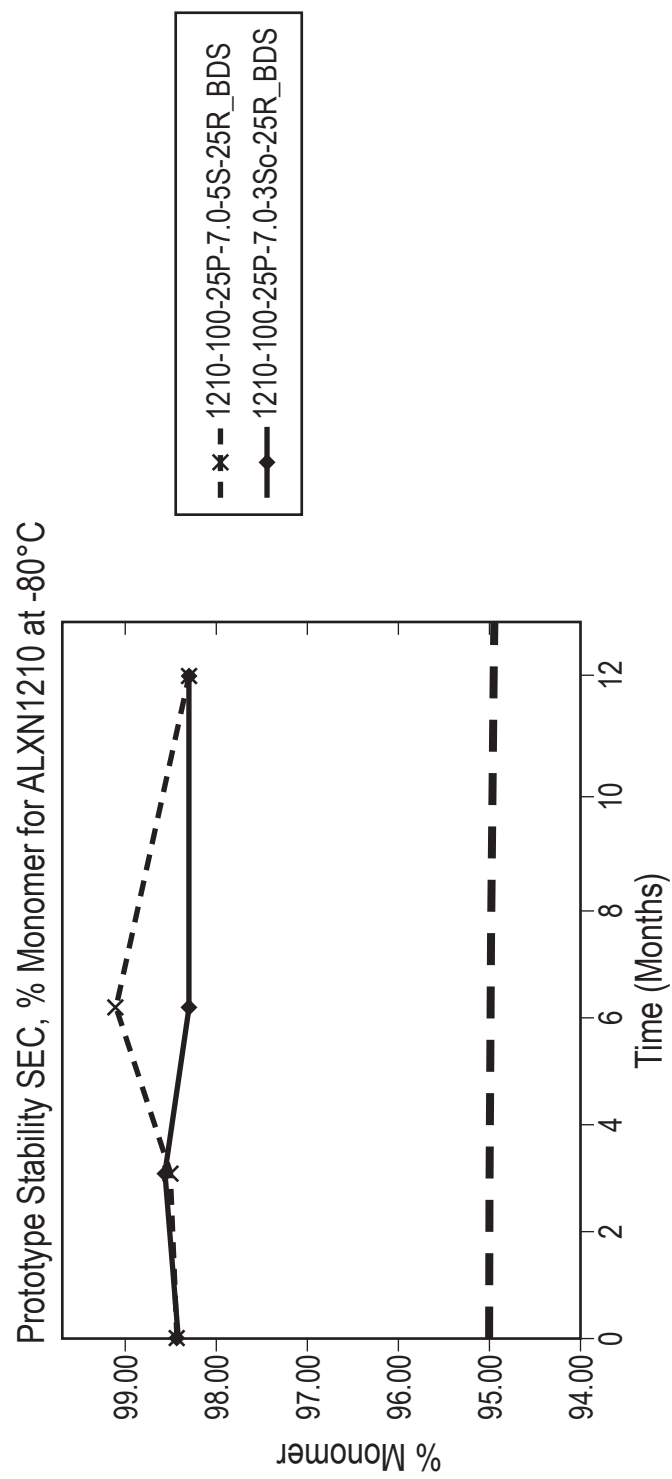


FIG. 37

Prototype Stability Dynamic Light Scattering ALXN1210
Phosphate Samples at 75 mg/mL T=0

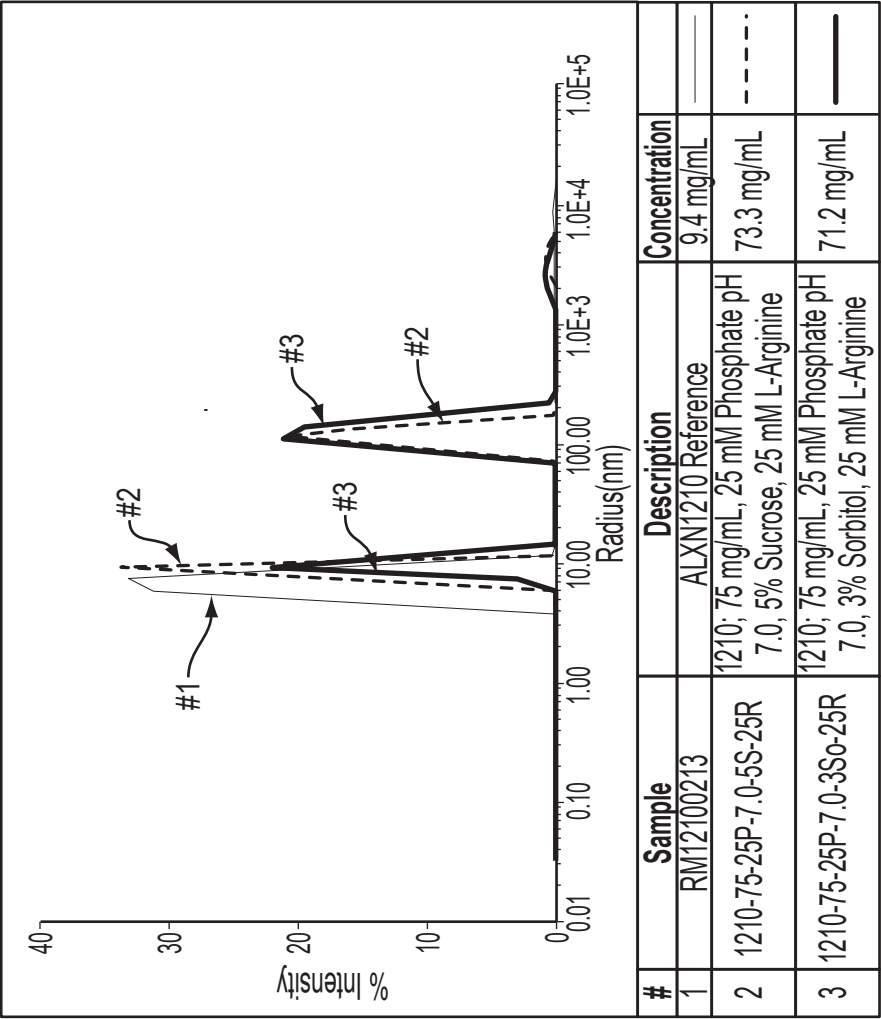


FIG. 38

Prototype Stability Dynamic Light Scattering ALXN1210
Phosphate Samples at 75 mg/mL T=1 Month 2-8°C

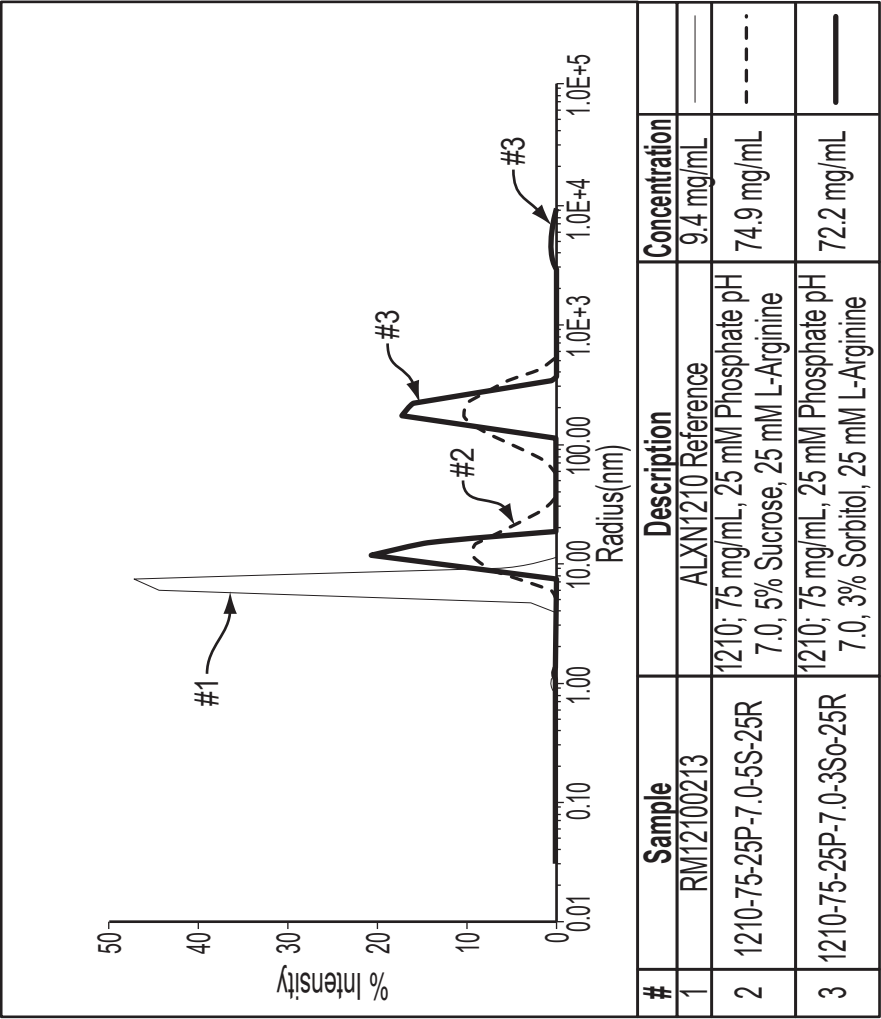


FIG. 39

Prototype Stability Dynamic Light Scattering ALXN1210
Phosphate Samples at 100 mg/mL T=1 Month 2-8°C

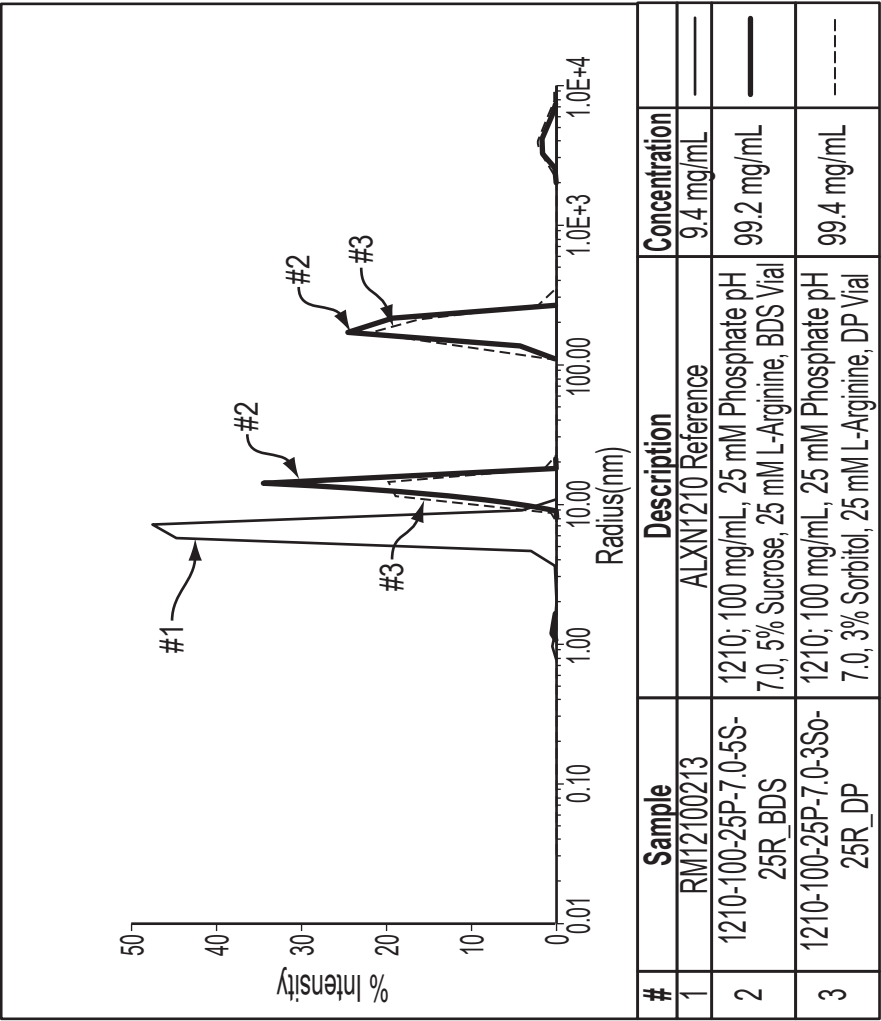


FIG. 40

Prototype Stability Study Results SEC, % Monomer for ALXN1210 -
Freeze Thaw Cycles 1-3 at T=1 Month -20°C (SPAS-14-007)

-20 °C		FT1				FT2			FT3			
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE	Appearance	Concentration (mg/mL)	SEC % Monomer	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	97.4	98.2	pl range 6.00-6.51	Slightly opalescent, practically free from particles	97.7	98.1	Slightly opalescent, practically free from particles	98.6	98.2	pl range 6.03-6.52
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	99.5	98.2	pl range 6.02-6.51	Slightly opalescent, practically free from particles	101.9	98.5	Slightly opalescent, practically free from particles	97.6	98.1	pl range 6.01-6.52

FIG. 41

-20 °C		FT4		FT5				
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	96.7	98.0	Slightly opalescent, practically free from particles	100	98.0	pl range 6.01-6.51
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	98.2	97.9	Slightly opalescent, practically free from particles	101.2	98.0	pl range 6.02-6.51

FIG. 42

Prototype Stability Study Results SEC, % Monomer for ALXN1210 -
Freeze Thaw Cycles 1-3 at T=3 Months -80°C (SPAS-14-007)

-80 °C		FT1				FT2				FT3			
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	pI range	Appearance	Concentration (mg/mL)	SEC % Monomer		Appearance	Concentration (mg/mL)	SEC % Monomer	pI range
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	100.6	98.5	pI range 6.01-6.51	Slightly opalescent, practically free from particles	99.5	98.2		Slightly opalescent, practically free from particles	99.2	98.3	pI range 6.01-6.51
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	101.8	98.6	pI range 6.02-6.51	Slightly opalescent, practically free from particles	101.2	98.1		Slightly opalescent, practically free from particles	101.3	98.1	pI range 6.00-6.51

FIG. 43

-80 °C		FT4			FT5			
Sample ID	Sample Description	Appearance	Concentration (mg/mL)	SEC % Monomer	Appearance	Concentration (mg/mL)	SEC % Monomer	ICE
1210-100-25P-7.0-5S-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 5% Sucrose, 25 mM L-Arginine, BDS	Slightly opalescent, practically free from particles	100.1	97.9	Slightly opalescent, practically free from particles	99.4	98.04	pl range 6.01-6.52
1210-100-25P-7.0-3So-25R_BDS	ALXN1210, 100 mg/mL, 25 mM Phosphate, pH 7.0, 3% Sorbitol, 25 mM L-Arginine, BDS		101	98.0		100.7	98.00	pl range 6.01-6.51

FIG. 44

Prototype Stability SEC, % Monomer for ALXN1210
Freeze Thaw Cycle 1-5 at T=1 Month -20°C (SPAS-14-007)

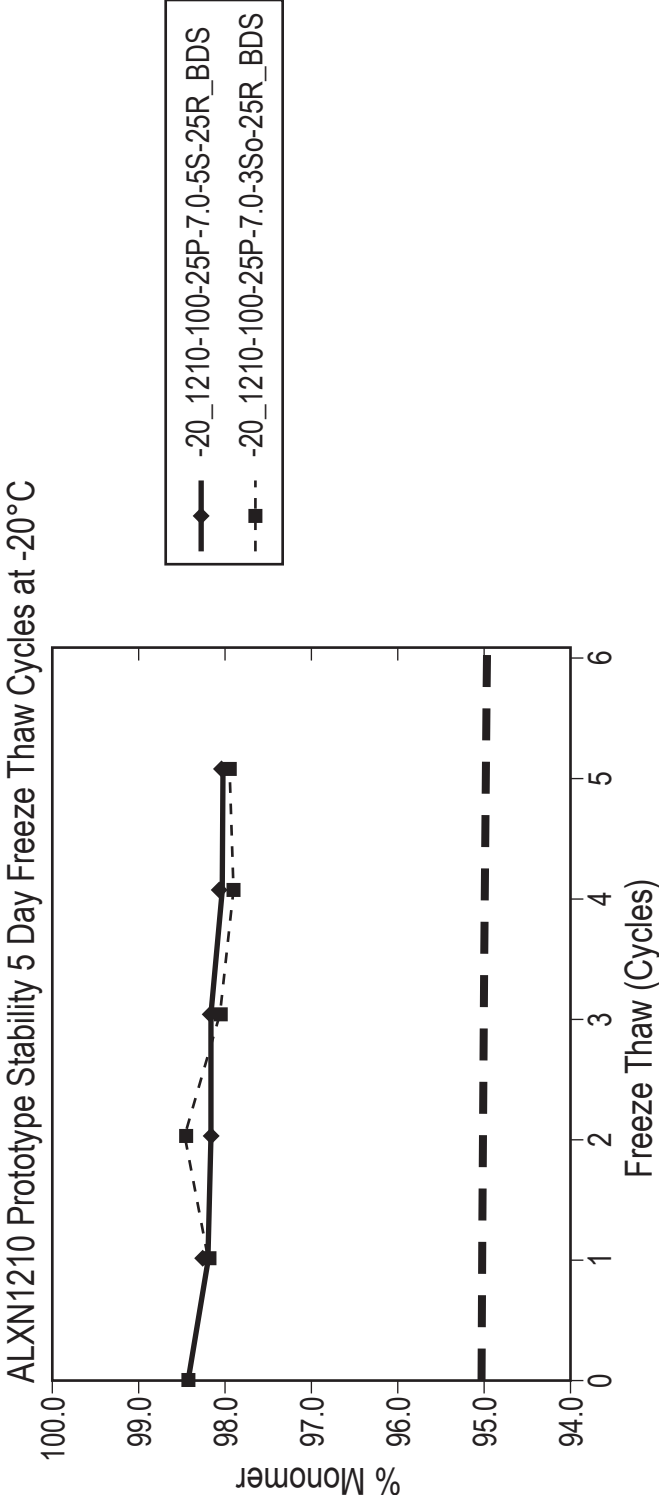


FIG. 45

Prototype Stability SEC, % Monomer for ALXN1210
Freeze Thaw Cycle 1-5 at T=3 Months -80°C (SPAS-14-007)

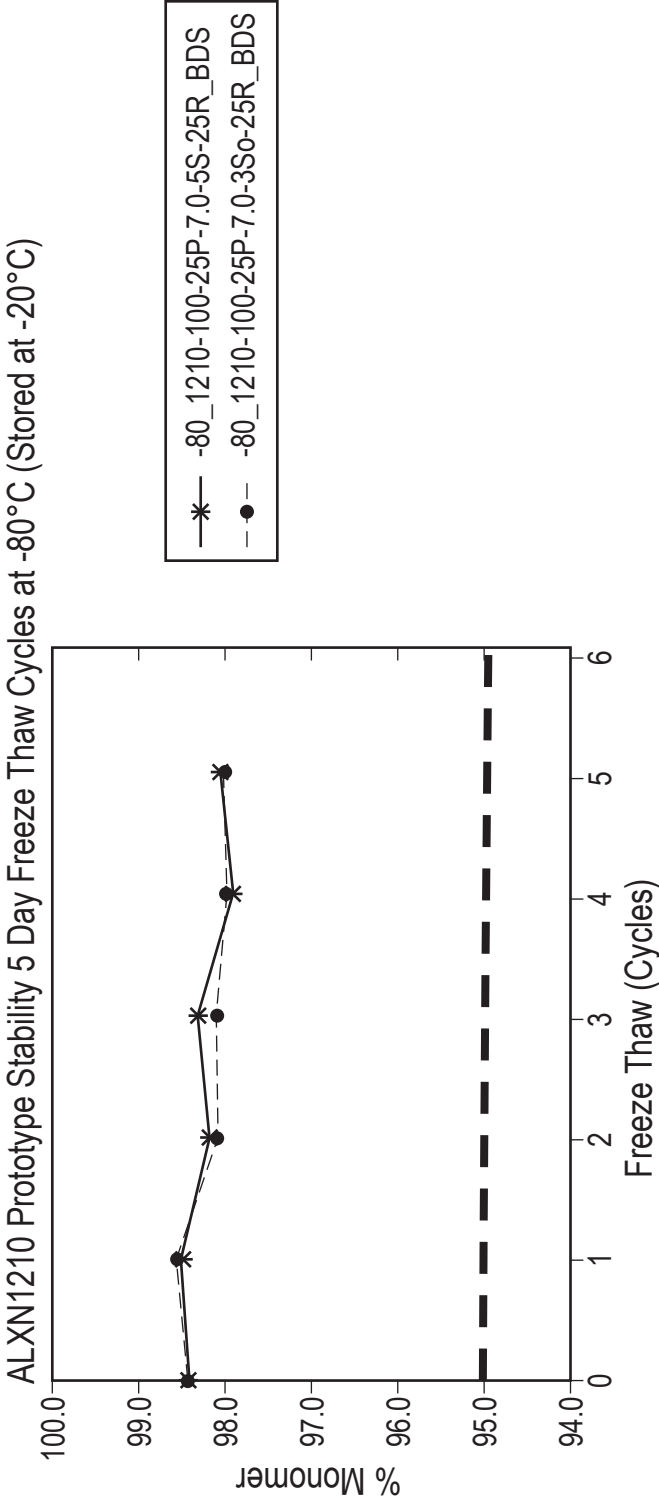
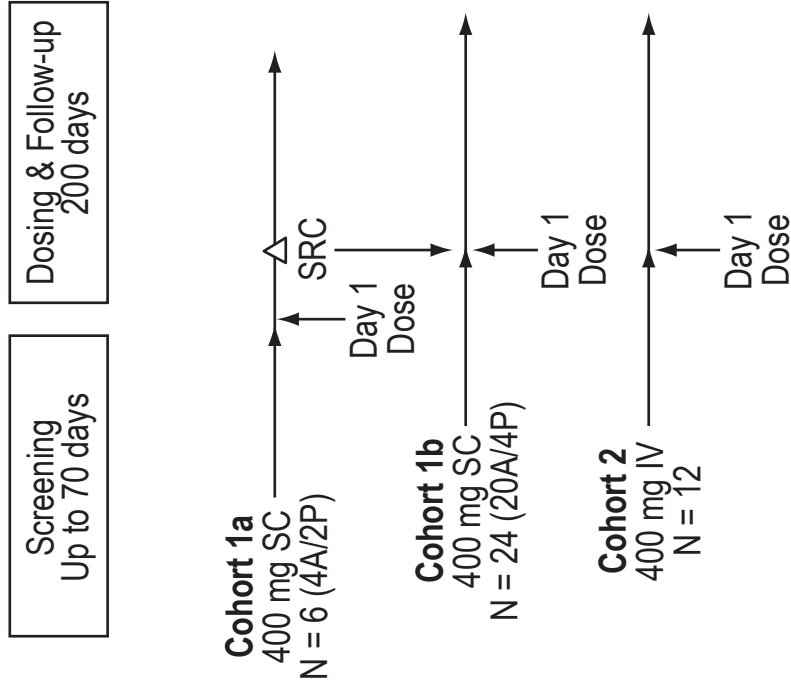


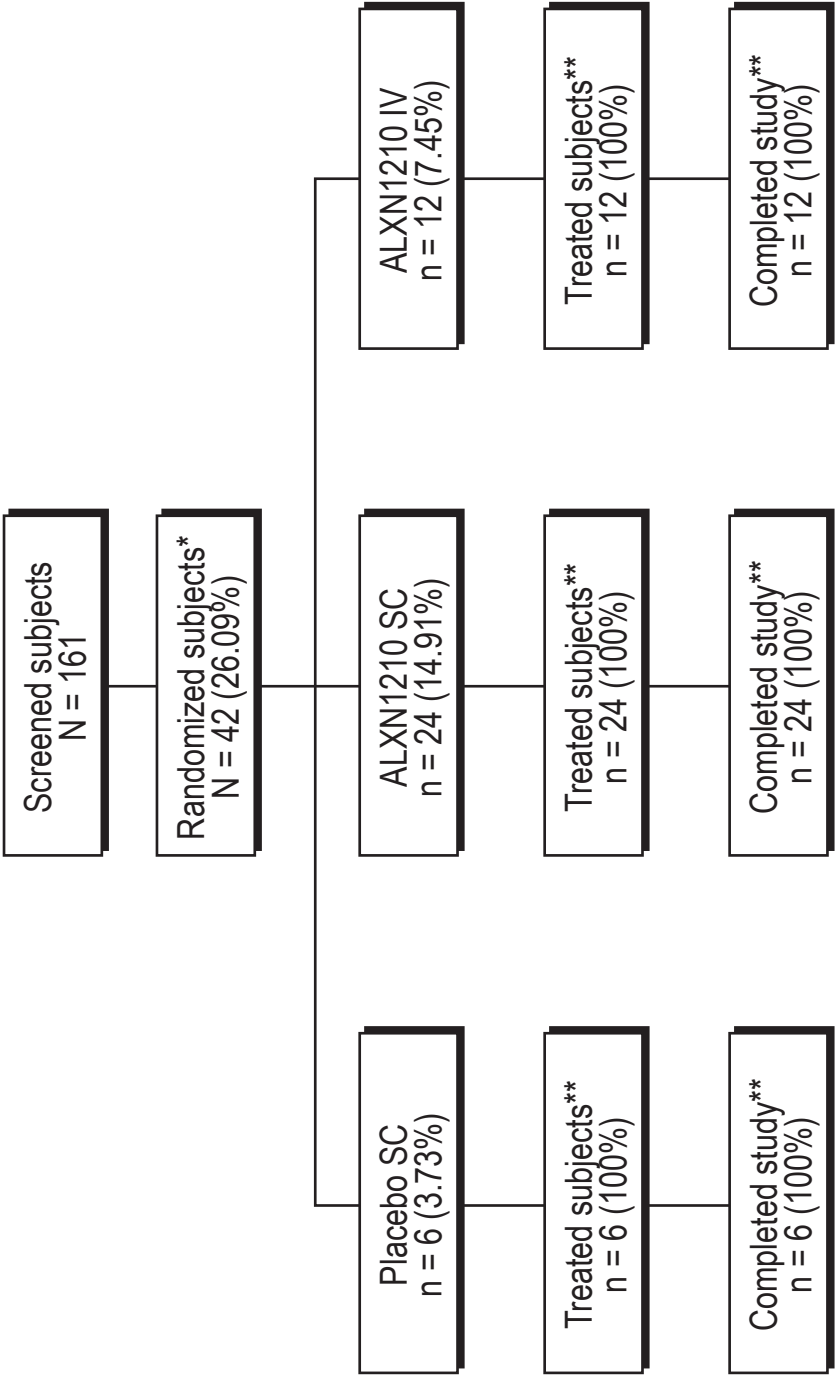
FIG. 46



Abbreviations: A = active drug; IV = intravenous; P = placebo; SC = subcutaneous; SRC = Safety Review Committee
Note: The SRC will review the first 48 hours of post-dose safety data from Cohort 1a before enrollment into Cohorts 1b or 2 may begin.

FIG. 47

Subject Disposition - All Subjects



*Percentages are based on the number of screened subjects.

** Percentages are based on the number of randomized subjects within each treatment group.
Abbreviations: IV = intravenous; N = total number of subjects; n = number of subjects; SC = subcutaneous.

FIG. 48

Mean ($\pm$ SD) Serum Concentration Versus Time Profiles
(Pharmacokinetic Set) - Linear Scale

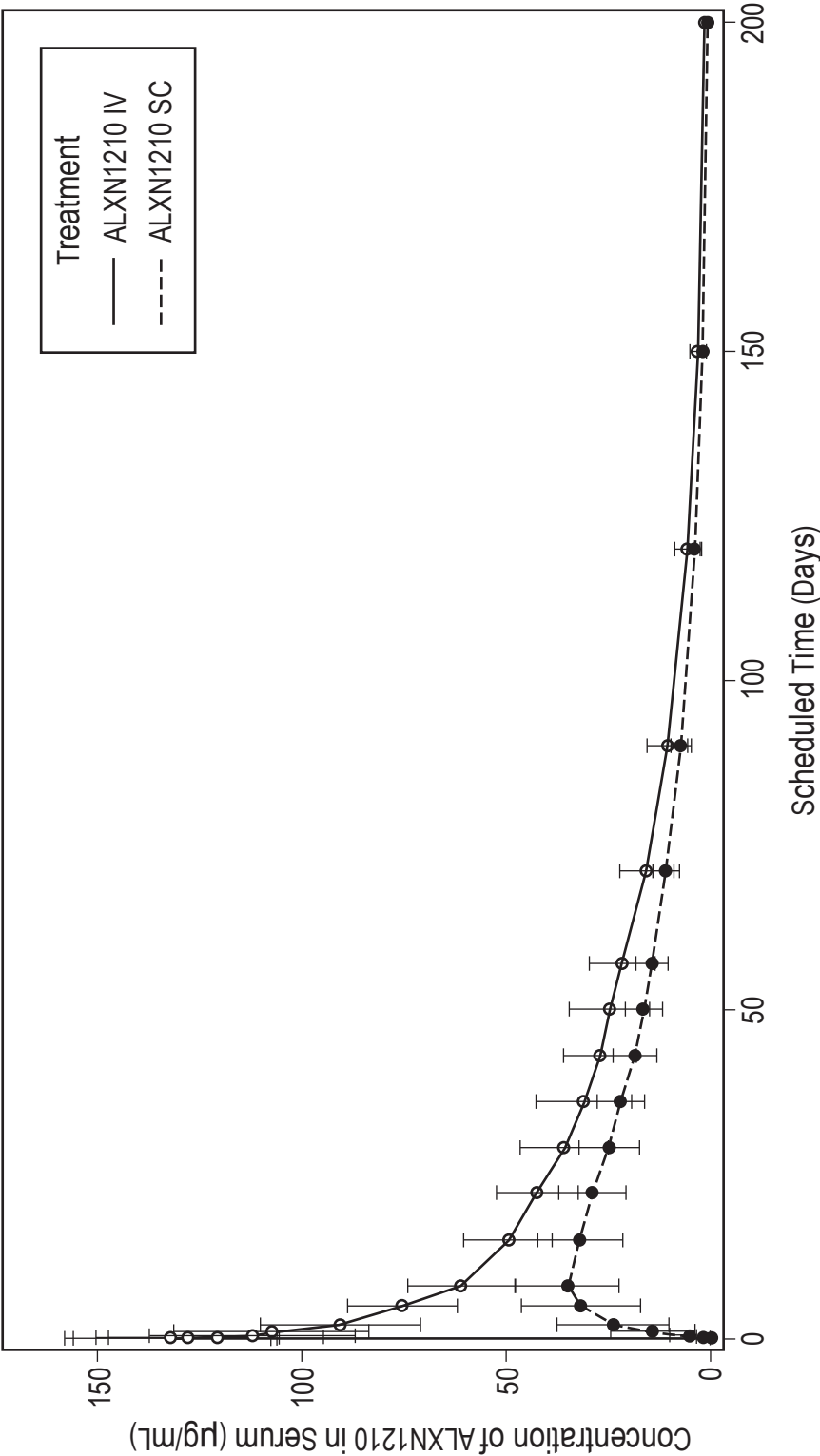


FIG. 49

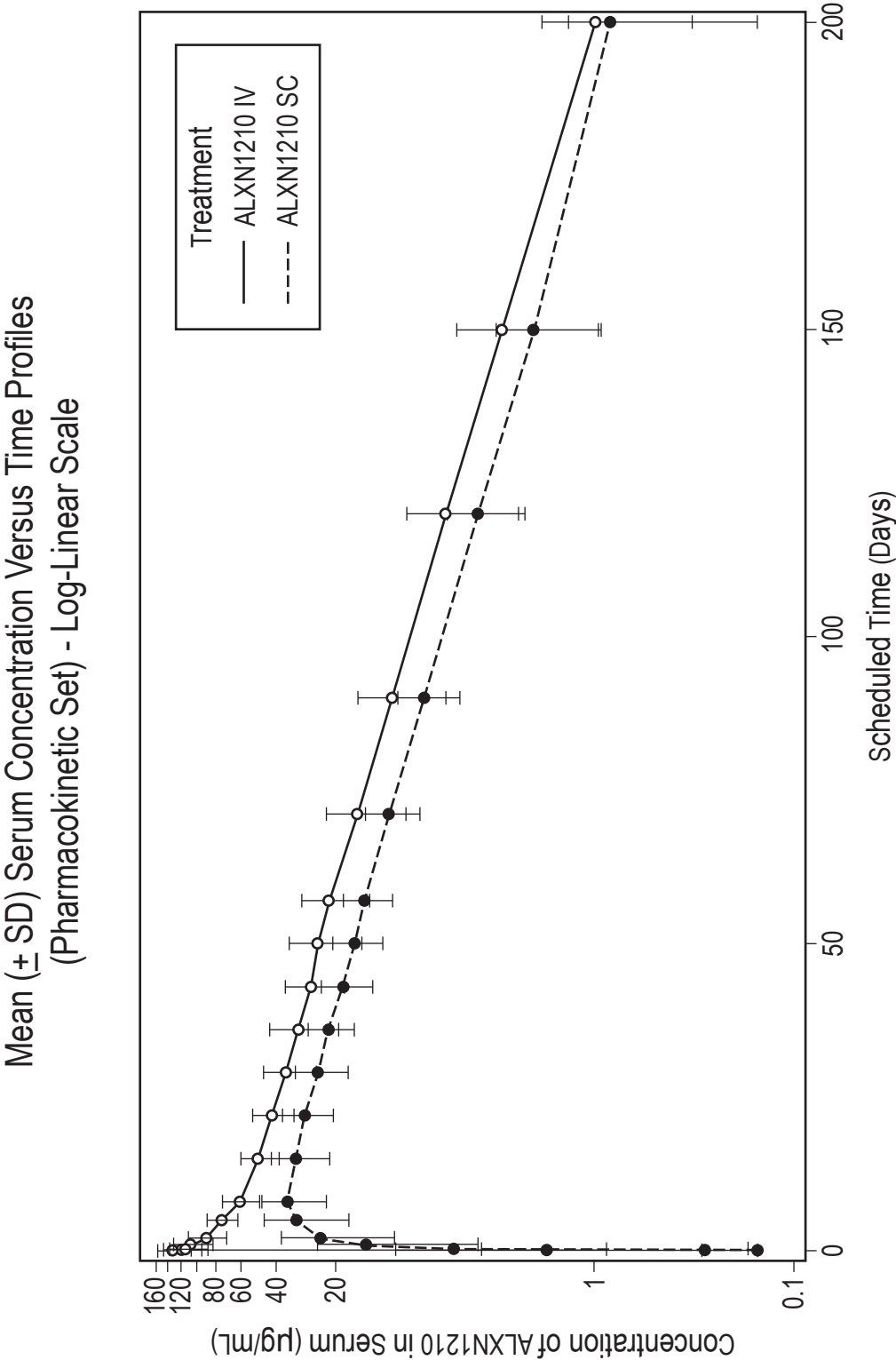


FIG. 50

Free Complement C5 Serum Concentration
Mean ($\pm$ SD) Percentage Change from
Baseline Versus Nominal Time
(Pharmacodynamic Set)

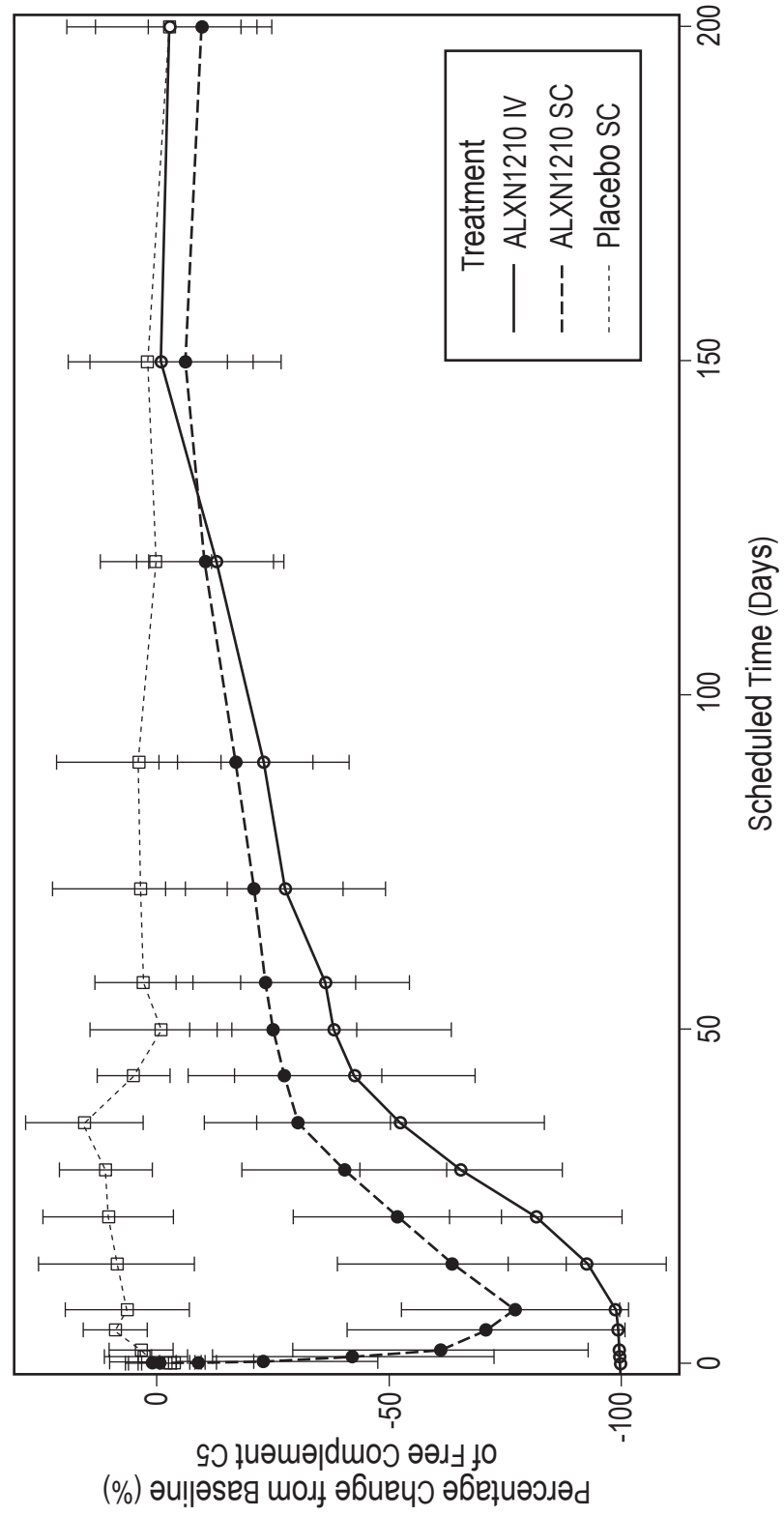


FIG. 51

Total Complement C5 Serum Concentration Mean ($\pm$ SD)
Percentage Change from Baseline Versus Nominal Time
(Pharmacodynamic Set)

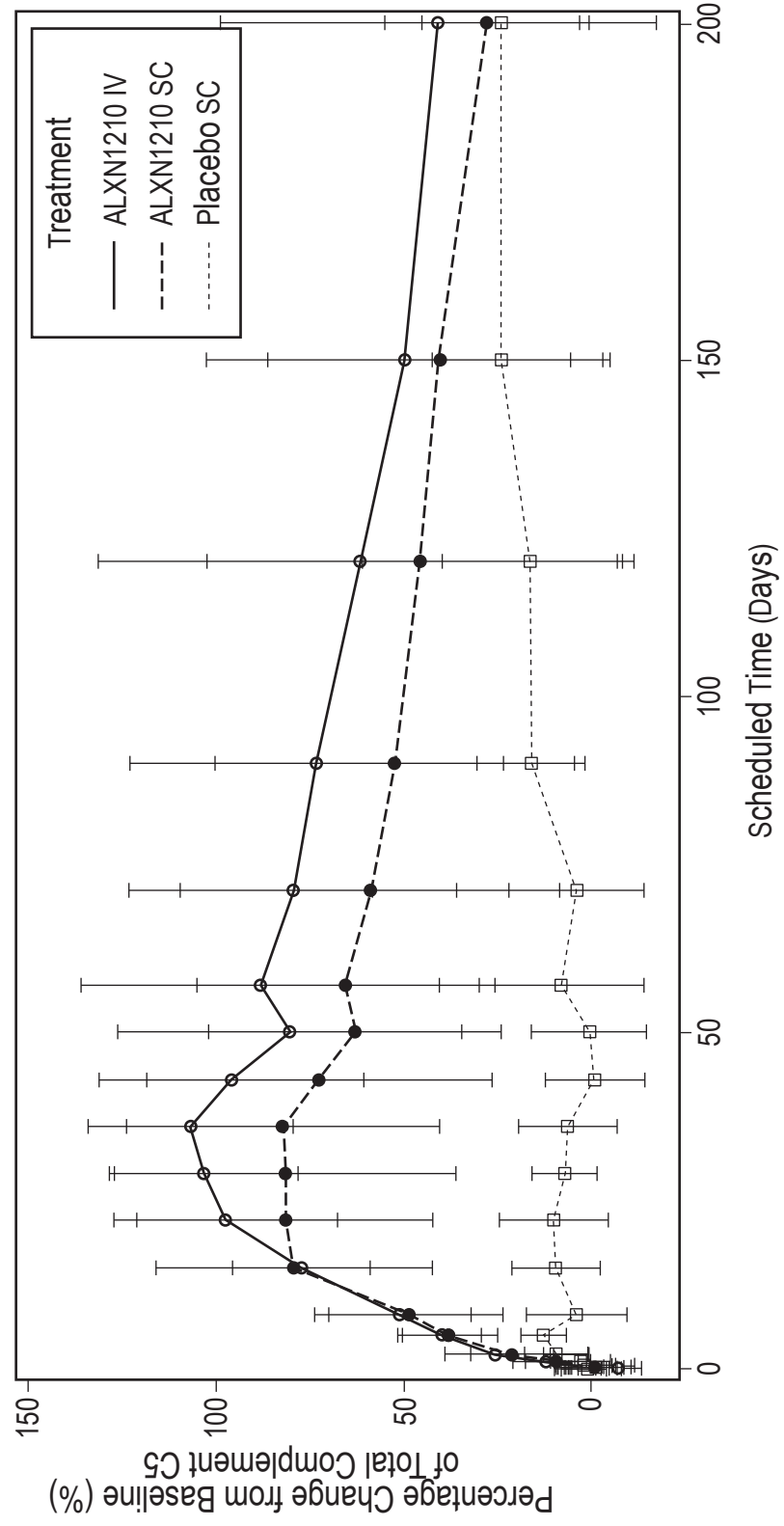


FIG. 52

Chicken Red Blood Cell Hemolysis (cRBC) Mean ($\pm$ SD)
Percentage Change from Baseline Versus Nominal Time
(Pharmacodynamic Set)

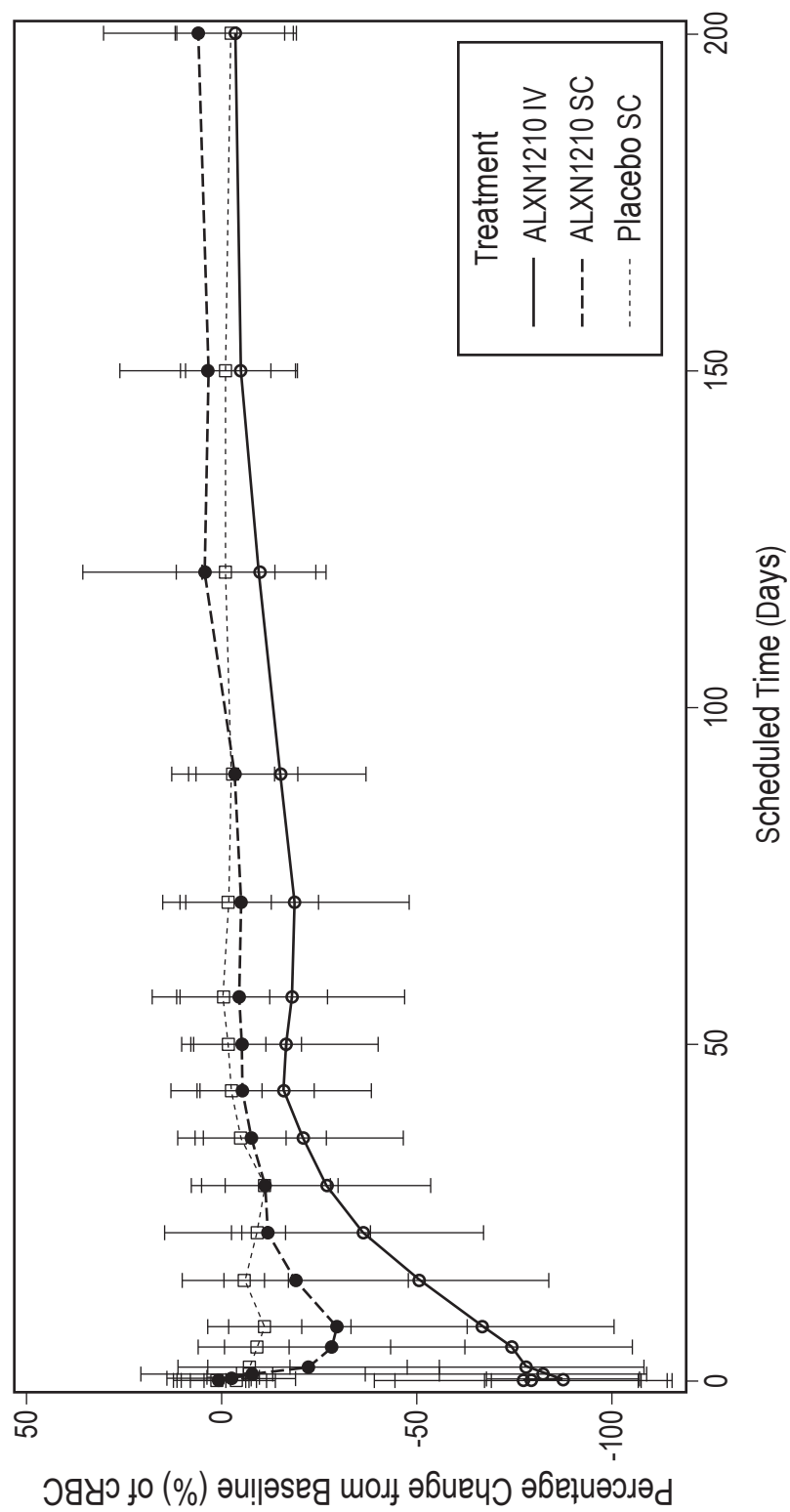


FIG. 53