Analysis	Sample	Result	Description
Digital imaging	F0		White particulate matter can be observed
Digital Imaging	F0 5x F/T		Large amounts of white particle matter can be observed
Digital Imaging	F0 after 1M at 25 °C		Large amounts of white particle matter can be observed

FIG. 1A

Polarized Light Microscopy	F0 after 1M at 25 °C	Plane polarized Crossed Polars	No birefringence seen under crossed-polars suggesting the material is either isotropic or amorphous

FIG. 1B

SEM/EDS	F0 5x F/T	There are large proportions of O, Ca and P in the sample

FIG. 1C

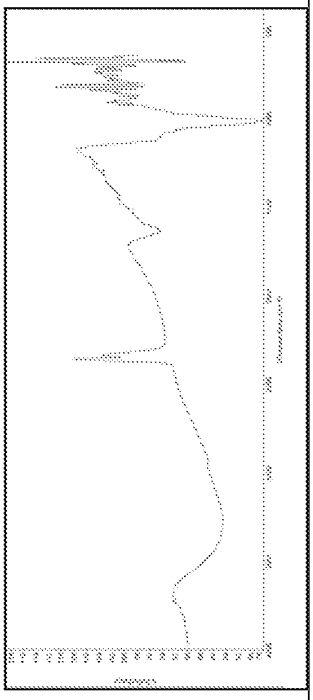
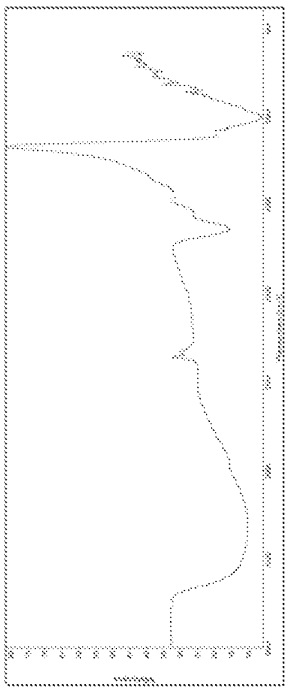
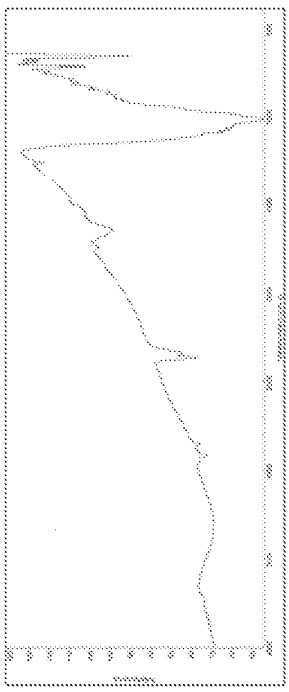
FTIR	F0		FTIR suggest material is a salt from database search. F0, F0 5x F/T, and F0 1 M at 25°C samples all show similar spectra.
FTIR	F0 5x F/T		FTIR suggest material is a salt from database search. F0, F0 5x F/T, and F0 1 M at 25°C samples all show similar spectra.
FTIR	F0 after 1M at 25°C		FTIR suggest material is a salt from database search. F0, F0 5x F/T, and F0 1 M at 25°C samples all show similar spectra.

FIG. 1D

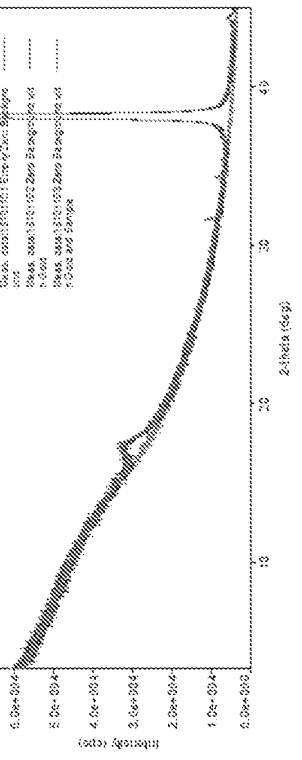
XRD	F0 after 1M at 25°C		Peaks appear under XRD suggesting there is some crystallinity in the sample

FIG. 1E

Digital Imaging	F0 5x F/T (lot 2)	White particle matter observed
FTIR	F0 5x F/T (lot 2)	Resembles spectra for F0 from previous lot
Raman microscopy	F0 5x F/T	Material identified as calcium phosphate

FIG. 1F

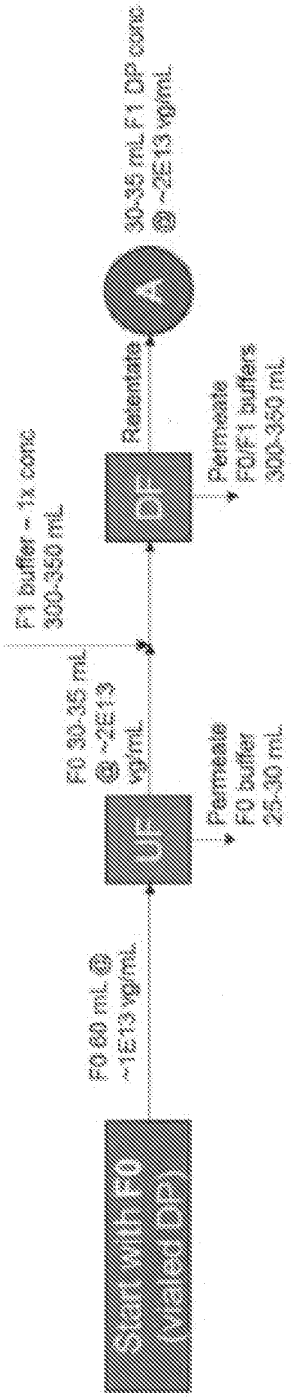

Start with F0 crude lysate
F0 60 mL @ ~1E13 vg/mL
TFF
Permeate F0 buffer 25-30 mL
F0 30-35 mL @ ~2E13 vg/mL
F1 buffer ~ 1x conc 300-350 mL
DF
Permeate F0/F1 buffers 300-350 mL
Retentate
A
30-35 mL F1 DP conc @ ~2E13 vg/mL

FIG. 2

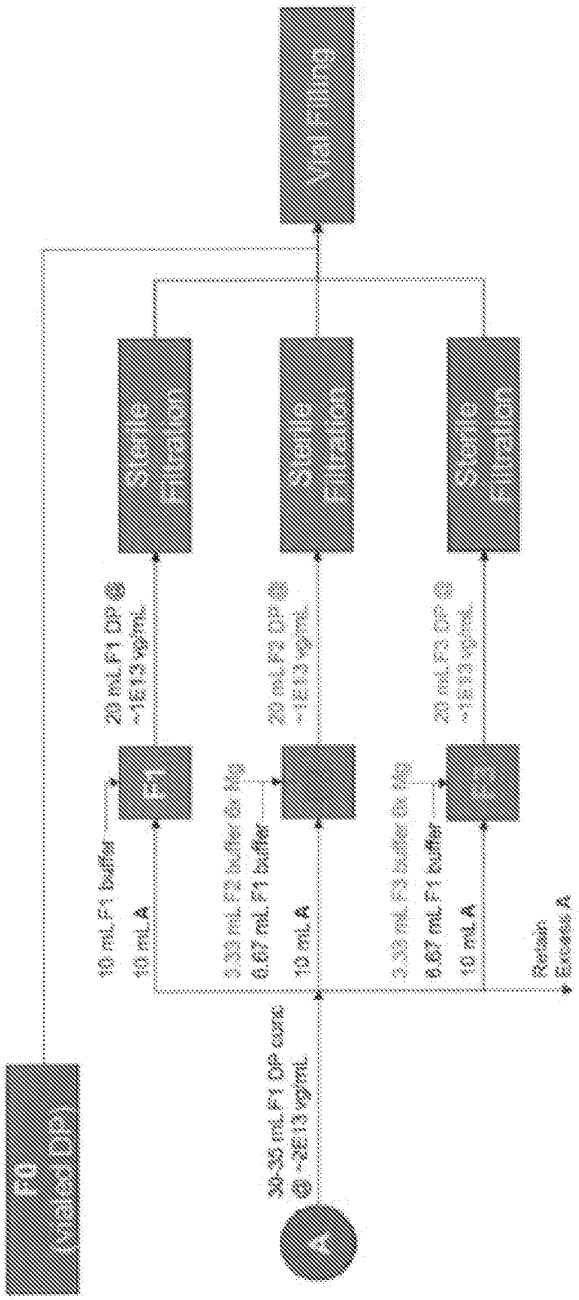

F0 material
A
30-35 mL F1 DP conc @ ~2E13 vg/mL
10 mL F1 buffer
10 mL A
F1
20 mL F1 DP @ ~1E13 vg/mL
Sterile Filtration
3.33 mL F2 buffer to Hg
6.67 mL F1 buffer
10 mL A
F2
20 mL F2 DP @ ~1E13 vg/mL
Sterile Filtration
3.33 mL F3 buffer to Hg
6.67 mL F1 buffer
10 mL A
F3
20 mL F3 DP @ ~1E13 vg/mL
Sterile Filtration
Retain Excess A
Vial Filling

FIG. 3

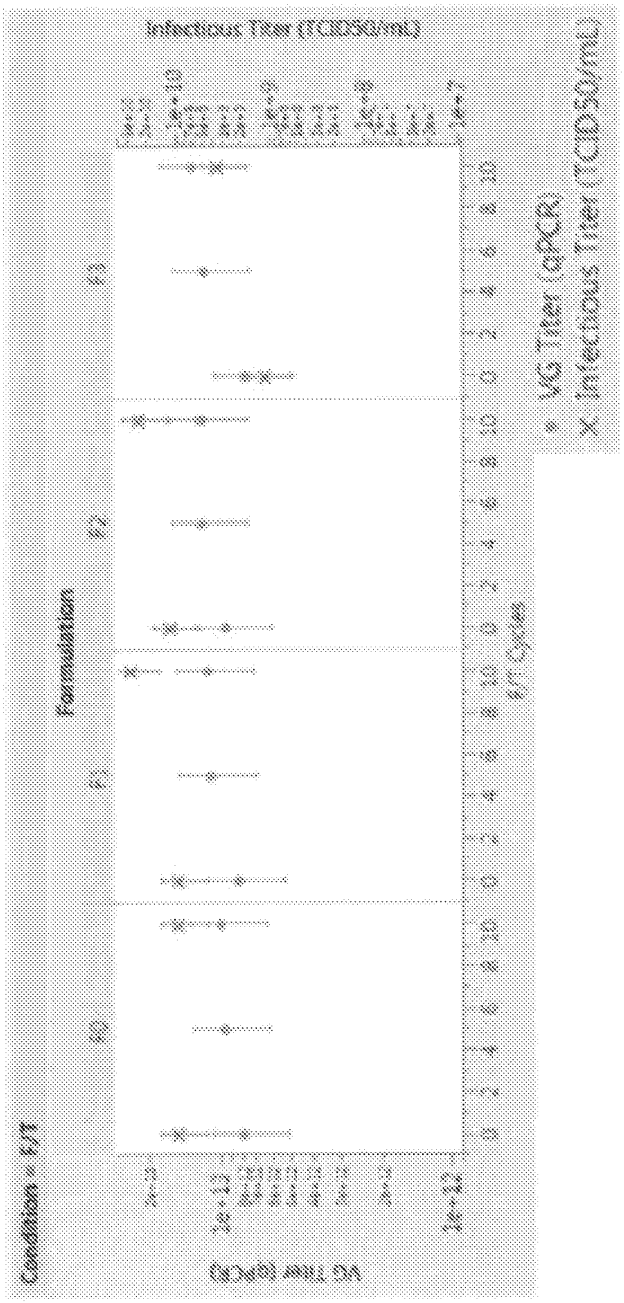

Infectious Titer (TCID50/mL)
VG Titer (gPCR)
* VG Titer (qPCR)
x Infectious Titer (TCID50/mL)
Formulation
F3
F2
F1
F0
Condition = 5/8
VG Titer (gPCR)
Infectious Titer (TCID50/mL)
Freeze/Thaw Cycles

FIG. 4A

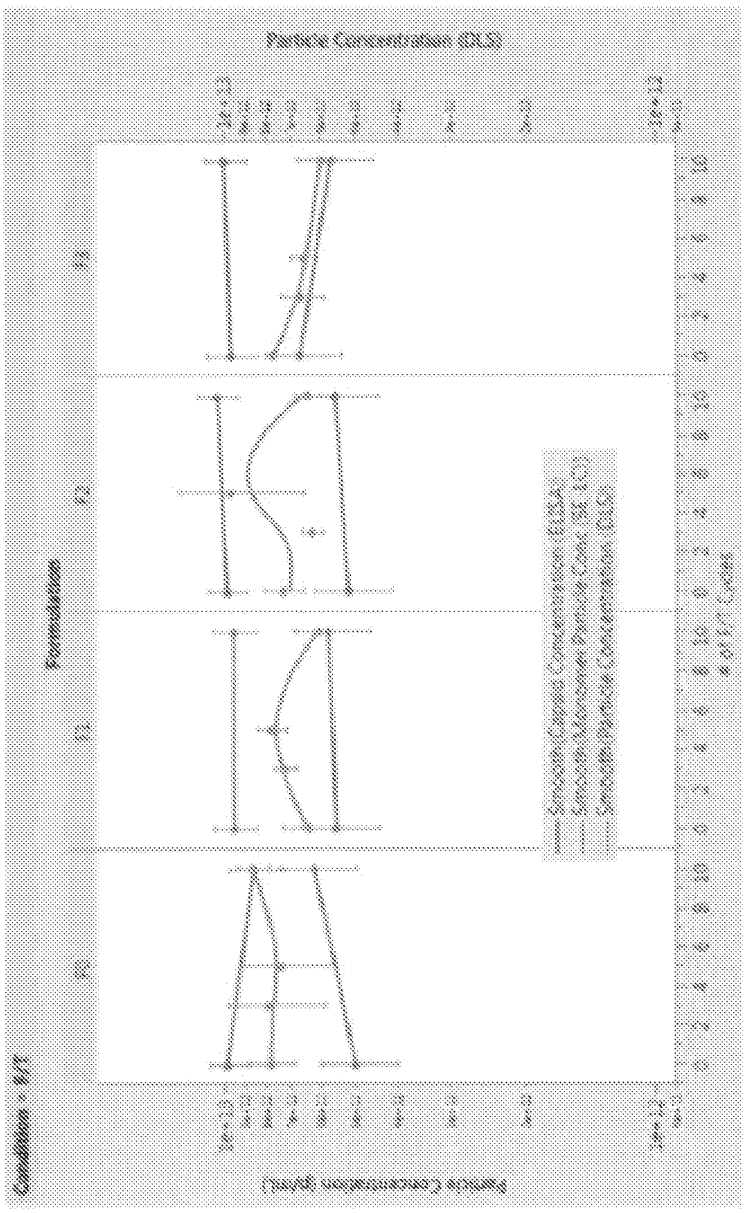

Particle Concentration (#/L)
Particle Concentration (#/mL)
Condition = 0.5
Formulations
F1
F2
F3
F4
Emulsion Droplet Concentration (EDC)
Emulsion Microsphere Particle Count (EM PC)
Emulsion Particle Concentration (EPC)
Particle Count
#/EM PC Count

FIG. 4B

Formulation	Condition	Appearance	pH	Monomer Peak Mean Size (nm)	Polydisp. Index	% Monomer DLS	% HMWS, DLS	% HMWS, SE-LC	% Full Capsids
F0	**Initial**	**Pass**	**7.3**	29.7	0.07	100.0%	0%	**0.2%**	**89.2%**
	3x F/T	Pass	7.3	30.7	0.12	99.6%	0.4%	ND	ND
	5x F/T	Fail	7.3	30.4	0.08	100.0%	0%	ND	ND
	10x F/T	**Fail**	**7.3**	30.2	0.07	100.0%	0%	**0.0%**	**89.3%**
F1	**Initial**	**Pass**	**7.3**	33.0	0.12	100.0%	0%	**0.5%**	**89.1%**
	3x F/T	Pass	7.2	32.8	0.13	100.0%	0%	ND	ND
	5x F/T	Pass	7.2	34.3	0.13	100.0%	0%	ND	ND
	10x F/T	**Pass**	**7.3**	33.4	0.12	100.0%	0%	**0.6 %**	**89.2%**
F2	**Initial**	**Pass**	**7.2**	33.6	0.14	100.0%	0%	**0.5%**	**89.3%**
	3x F/T	Pass	7.2	34.0	0.14	100.0%	0%	ND	ND
	5x F/T	Pass	7.3	33.9	0.13	100.0%	0%	ND	ND
	10x F/T	**Pass**	**7.2**	33.6	0.13	100.0%	0%	**0.5%**	**89.3%**
F3	**Initial**	**Pass**	**7.2**	33.4	0.12	100.0%	0%	**0.4%**	**89.1%**
	3x F/T	Pass	7.2	33.3	0.12	100.0%	0%	ND	ND
	5x F/T	Pass	7.2	33.6	0.13	100.0%	0%	ND	ND
	10x F/T	**Pass**	**7.3**	33.7	0.13	100.0%	0%	**0.3%**	**89.0%**

ND: No data.

FIG. 4C

Formulation	Condition	VG Titer (vg/mL)	Infectious Titer ($TCID_{50}$/mL)	VG/$TCID_{50}$	Capsid Titer (capsids/mL)	Monomer Conc, SE-LC (p/mL)	Monomer Conc, MADLS (p/mL)
F0	**Initial**	**7.9E+12**	**9.3E+09**	**1200**	**5.0E+12**	**1.0E+13**	**7.8E+12**
	3x F/T	ND	ND	ND	ND	ND	8.3E+12
	5x F/T	9.5E+12	ND	ND	ND	ND	8.3E+12
	10x F/T	**9.9E+12**	**9.3E+09**	**700**	**6.2E+12**	**8.6E+12**	**7.8E+12**
F1	**Initial**	**8.3E+12**	**9.3E+09**	**1100**	**5.5E+12**	**9.5E+12**	**6.4E+12**
	3x F/T	ND	ND	ND	ND	ND	6.7E+12
	5x F/T	1.1E +13	ND	ND	NO	ND	7.0E+12
	10x F/T	**1.1E+13**	**2.9E+10**	**300**	**5.7E+12**	**9.5E+12**	**5.9E+12**
F2	**Initial**	**9.4E+12**	**1.1E+10**	**1100**	**5.2E+12**	**9.9E+12**	**7.3E+12**
	3x F/T	ND	ND	ND	ND	ND	6.8E+12
	5x F/T	1.2E+13	ND	ND	ND	ND	1.0E+13
	10x F/T	**1.2E+13**	**2.4E+10**	**400**	**5.6E+12**	**1.0E+13**	**6.4E+12**
F3	**Initial**	**7.7E+12**	**1.1E+09**	**8400**	**6.7E+12**	**9.7E+12**	**8.2E+12**
	3x F/T	ND	ND	ND	ND	ND	6.1E+12
	5x F/T	1.8E+13	ND	ND	ND	ND	6.0E+12
	10x F/T	**1.3E+13**	**3.6E+09**	**2600**	**5.7E+12**	**1.0E+13**	**5.7E+12**

FIG. 4D

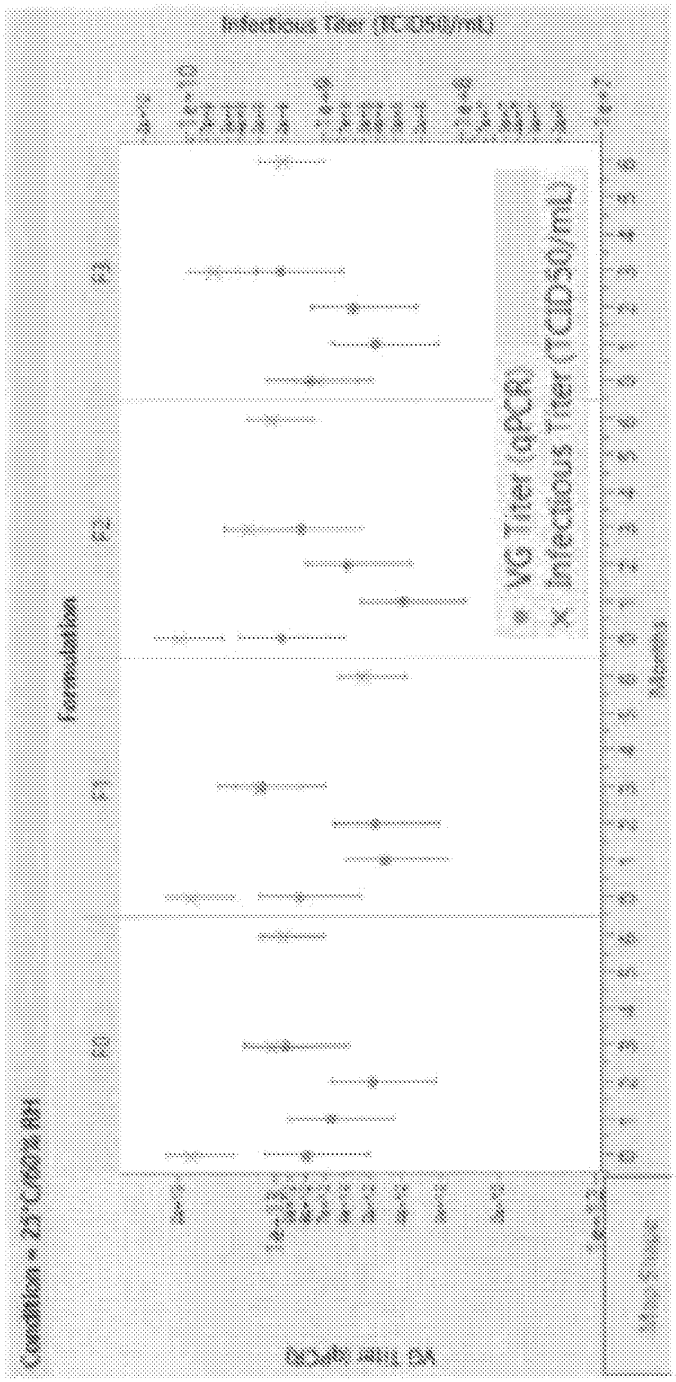

Infectious Titer (TCID50/mL)
VG Titer (qPCR)
Infectious Titer (TCID50/mL)
Formulation
F3
F2
F1
F0
Condition = 25°C/60% RH
Time (Days)

FIG. 5A

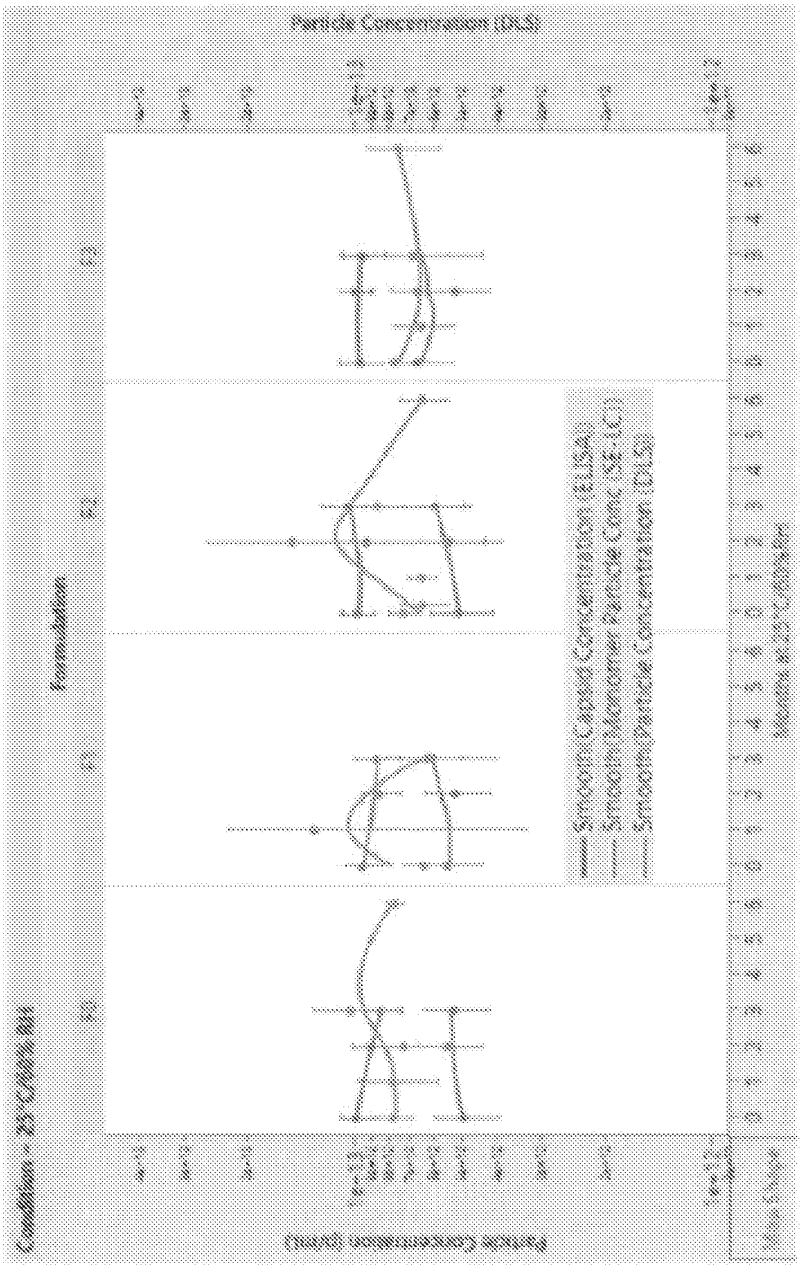

Particle Concentration (DLS)
Condition = 25°C/60% RH
Formulation
F3
F2
F1
F0
Stream Capsid Concentration (ELISA)
Stream Monomer Particle Conc. (SEC)
Stream Particle Concentration (DLS)
Particle Concentration (Capsid)
Time (Days)

FIG. 5B

Formulation	Condition	Appearance	pH	Monomer Peak Mean Size (nm)	Polydisp. Index	% Monomer, DLS	% HMWS, DLS	% HMWS, SE-LC	% Full Capsids
F0	**Initial**	**Pass**	**7.3**	**29.7**	**0.07**	**100.0%**	**0.0%**	**0.2%**	**89.2%**
	1 week	Pass	7.3	ND	ND	ND	ND	ND	ND
	1 month	Pass	7.3	30.2	0.08	100.0%	0.0%	ND	ND
	2 months	Pass	7.2	30.1	0.07	100.0%	0.0%	0.7%	NAA
	3 months	**Pass**	**7.4**	**32.9**	**0.13**	**100.0%**	**0.0%**	**0.0%**	**NAA**
	6 months	Pass	7.2	30.6	0.08	100.0%	0.0%	ND	ND
F1	**Initial**	**Pass**	**7.3**	**33.0**	**0.12**	**100.0%**	**0.0%**	**0.5%**	**89.1%**
	1 week	Pass	7.1	ND	ND	ND	ND	ND	ND
	1 month	Pass	7.2	34.3	0.14	100.0%	0.0%	ND	ND
	2 months	Pass	7.2	34.4	0.14	100.0%	0.0%	1.9%	NAA
	3 months	**Pass**	**7.2**	**36.4**	**0.17**	**99.6%**	**0.4%**	**5.5%**	**NAA**
	6 months	Pass	7.2	ND	ND	ND	ND	ND	ND
F2	**Initial**	**Pass**	**7.2**	**33.6**	**0.14**	**100.0%**	**0.0%**	**0.5%**	**89.3%**
	1 week	Pass	7.2	ND	ND	ND	ND	ND	ND
	1 month	Pass	7.2	34.2	0.13	100.0%	0.0%	ND	ND
	2 months	Pass	7.2	34.6	0.14	100.0%	0.0%	0.8%	NAA
	3 months	**Pass**	**7.2**	**35.4**	**0.17**	**99.5%**	**0.5%**	**1.3%**	**NAA**
	6 months	Pass	7.3	34.0	0.13	100.0%	0.0%	ND	ND
F3	**Initial**	**Pass**	**7.2**	**33.4**	**0.12**	**100.0%**	**0.0%**	**0.4%**	**89.1%**
	1 week	Pass	7.2	ND	ND	ND	ND	ND	ND
	1 month	Pass	7.3	33.6	0.13	100.0%	0.0%	ND	ND
	2 months	Pass	7.2	33.5	0.12	100.0%	0.0%	0.6%	NAA
	3 months	**Pass**	**7.4**	**34.7**	**0.17**	**99.2%**	**0.8%**	**1.7%**	**NAA**
	6 months	Pass	7.2	33.9	0.13	100.0%	0.0%	ND	ND

FIG. 5C

Formulation	Condition	VG Titer (vg/mL)	Infectious Titer ($TCID_{50}$/mL)	VG/$TCID_{50}$	Capsid Titer (capsids/mL)	Monomer Conc, SE-LC (p/mL)	Monomer Conc, MADLS (p/mL)
F0	**Initial**	**7.9E+12**	**9.3E+09**	**1200**	**5.0E+12**	**1.0E+13**	**7.8E+12**
	1 month	6.6E+12	ND	ND	ND	ND	8.6E+12
	2 months	4.9E+12	ND	ND	5.5E+12	9.0E+12	8.4E+12
	3 months	**9.2E+12**	**2.4E+09**	**1100**	**5.3E+12**	**8.4E+12**	**8.6E+12**
	6 months	ND	2.0E+09	ND	ND	ND	7.7E+12
F1	**Initial**	**8.3E+12**	**9.3E+09**	**1100**	**5.5E+12**	**9.5E+12**	**6.4E+12**
	1 month	4.5E+12	ND	ND	ND	ND	1.2E+13
	2 months	4.8E+12	ND	ND	5.3E+12	8.6E+12	1.5E+13
	3 months	**1.1E+13**	**2.9E+09**	**600**	**6.3E+12**	**8.7E+12**	**4.8E+12**
	6 months	ND	5.2E+08	ND	ND	ND	ND
F2	**Initial**	**9.4E+12**	**1.1E+10**	**1100**	**5.2E+12**	**9.9E+12**	**7.3E+12**
	1 month	3.9E+12	ND	ND	ND	ND	6.7E+12
	2 months	5.9E+12	ND	ND	5.5E+12	9.3E+12	7.6E+12
	3 months	**8.2E+12**	**3.6E+09**	**1300**	**6.0E+12**	**1.1E+13**	**8.6E+12**
	6 months	ND	2.4E+09	ND	ND	ND	6.5E+12
F3	**Initial**	**7.7E+12**	**1.1 E+09**	**8400**	**6.7E+12**	**9.7E+12**	**8.2E+12**
	1 month	4.8E+12	ND	ND	ND	ND	6.5E+12
	2 months	5.6E+12	ND	ND	5.3E+12	1.0E+13	7.1E +12
	3 months	**9.5E+12**	**6.3E+09**	**500**	**6.8E+12**	**9.5E+12**	**7.3E+12**
	6 months	ND	2.0E+09	ND	ND	ND	7.5E+12

FIG. 5D

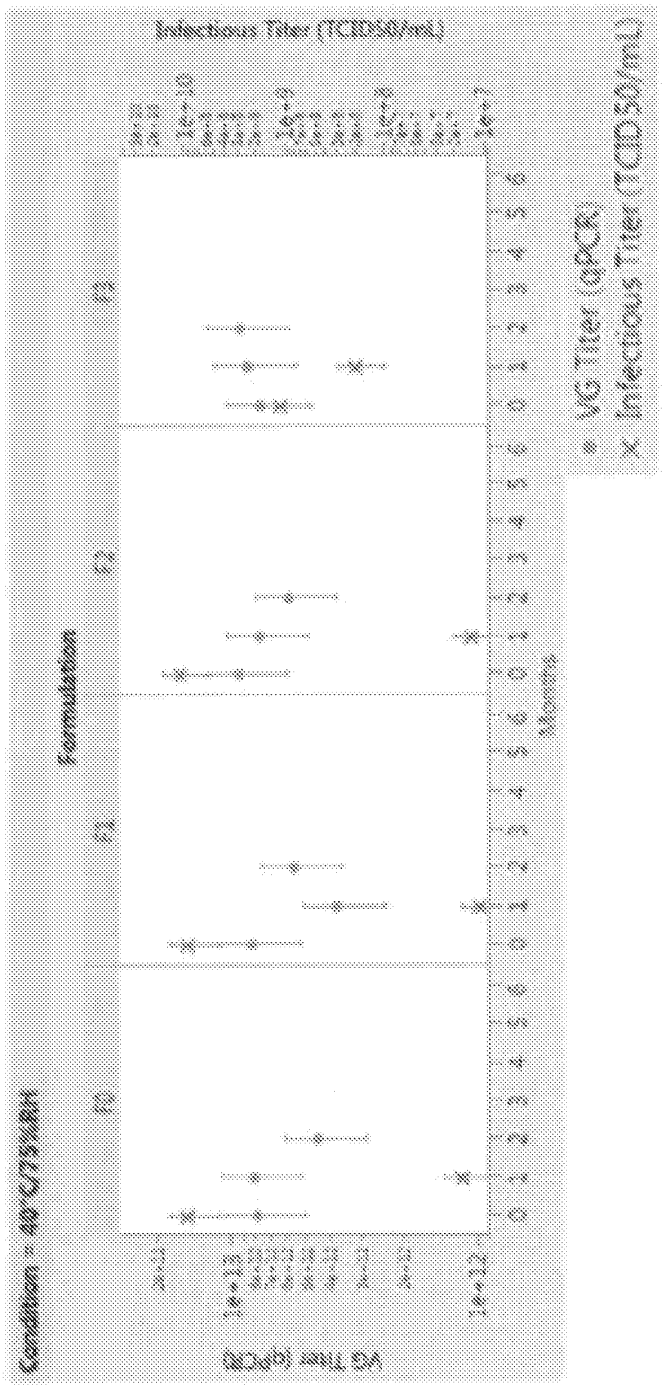

Condition = 40°C/75%RH
Formulation
F3
F2
F1
Months
VG Titer (qPCR)
Infectious Titer (TCID50/mL)
* VG Titer (qPCR)
× Infectious Titer (TCID50/mL)

FIG. 6A

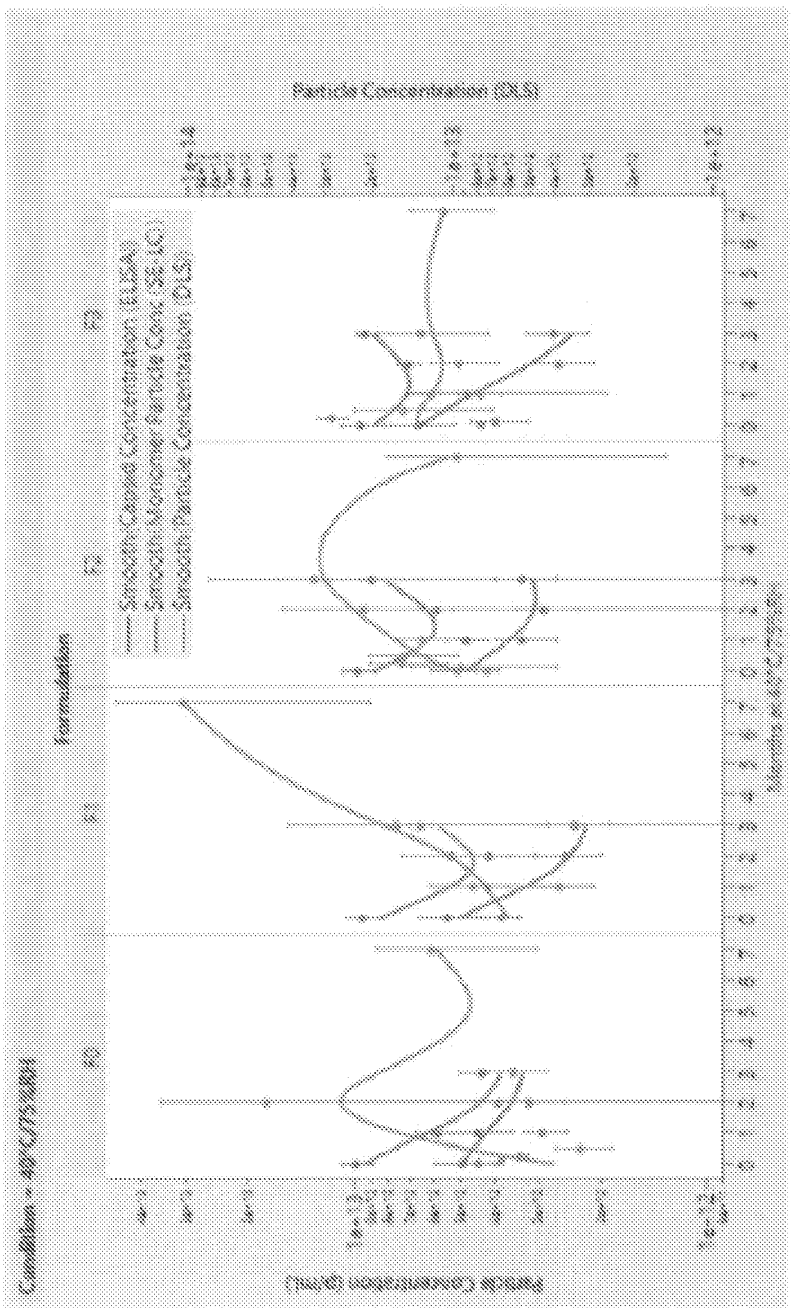

Particle Concentration (/cc)
Formulation
F3
F2
F1
Condition - 40°C/75%RH
Simulation Capsule Concentration (/cc)
Simulation Monomer Particle Conc (/cc)
Simulation Particle Concentration (/cc)
Simulation Capsule Concentration (/cc)
Simulation Monomer Particle Conc (/cc)
Simulation Particle Concentration (/cc)
Simulation Capsule Concentration (/cc)
Simulation Monomer Particle Conc (/cc)
Simulation Particle Concentration (/cc)

FIG. 6B

FIG. 6C

Formulation	Condition	Appearance	pH	Monomer Peak Mean Size (nm)	Polydisp. Index	% Monomer, DLS	% HMWS, DLS	% HMWS, SE-LC	% Full Capsids
F0	**Initial**	**Pass**	**7.3**	**29.7**	**0.07**	**100.0%**	**0.0%**	**0.2%**	**89.2%**
	3 days	Pass	7.3	34.1	0.15	99.6 %	0.4%	ND	ND
	1 week	Pass	7.4	35.0	0.14	100.0%	0.0%	ND	ND
	2 weeks	Pass	7.3	35.9	0.20	98.1%	1.9%	ND	ND
	1 month	**Pass**	**7.3**	**33.4**	**0.14**	**100.0%**	**0.0%**	**5.4%**	**NAA**
	2 months	Pass	7.1	28.8	0.36	94.6%	5.4%	0.0%	NAA
	3 months	Fail	7.1	32.6	0.32	87.6%	12.4%	0.0%	NAA
	7 months	ND	ND	32.8	0.50	72.7%	27.3%	ND	ND
F1	**Initial**	**Pass**	**7.3**	**33.0**	**0.12**	**100.0 %**	**0.0%**	**0.5%**	**89.1%**
	3 days	Pass	7.2	ND	ND	ND	ND	ND	ND
	1 week	Pass	7.2	ND	ND	ND	ND	ND	ND
	2 weeks	Pass	7.2	ND	ND	ND	ND	ND	ND
	1 month	**Pass**	**7.2**	**43.9**	**0.25**	**96.5%**	**3.6%**	**15.2%**	**NAA**
	2 months	Pass	7.2	40.6	0.22	98.5%	1.5%	4.5%	NAA
	3 months	Fail	7.2	41.7	0.24	96.9%	3.1%	20.3%	NAA
	7 months	ND	ND	46.7	0.24	99.0%	1.0%	ND	ND
F2	**Initial**	**Pass**	**7.2**	**33.6**	**0.14**	**100.0%**	**0.0%**	**0.5%**	**89.3%**
	3 days	Pass	7.2	39.5	0.22	96.6%	3.4%	ND	ND
	1 week	Pass	7.2	45.1	0.25	94.5%	5.5%	ND	ND
	2 weeks	Pass	7.2	42.2	0.26	92.6%	7.4%	ND	ND
	1 month	**Pass**	**7.2**	**41.3**	**0.23**	**97.6%**	**2.4%**	**6.5%**	**NAA**
	2 months	Pass	7.2	42.0	0.23	98.5%	1.5%	11.6%	NAA
	3 months	Fail	7.3	40.3	0.24	95.0%	5.0%	17.1%	NAA
	7 months	ND	ND	55.4	0.28	97.5%	2.5%	ND	ND
F3	**Initial**	**Pass**	**7.2**	**33.4**	**0.12**	**100.0%**	**0.0%**	**0.4%**	**89.1%**
	3 days	Pass	7.2	36.3	0.23	96.6%	3.4%	ND	ND
	1 week	Pass	7.2	40.2	0.20	98.4%	1.6%	ND	ND
	2 weeks	Pass	7.2	42.9	0.22	98.2%	1.8%	ND	ND
	1 month	**Pass**	**7.2**	**37.7**	**0.18**	**100.0%**	**0.0%**	**3.5%**	**NAA**
	2 months	Pass	7.2	37.9	0.20	98.9%	1.1%	5.6%	NAA

Formulation	Condition	Appearance	pH	Monomer Peak Mean Size (nm)	Polydisp. Index	% Monomer, DLS	% HMWS, DLS	% HMWS, SE-LC	% Full Capsids
	3 months	Fail	7.3	39.2	0.25	92.8%	7.2%	9.5%	NAA
	7 months	ND	ND	46.9	0.36	82.4%	17.6%	ND	ND

FIG. 6C (cont'd)

FIG. 6D

Formulation	Condition	VG Titer (vg/mL)	Infectious Titer ($TCID_{50}$/mL)	VG/$TCID_{50}$	Capsid Titer (capsids/mL)	Monomer Conc. SE-LC, (p/mL)	Monomer Conc. (MADLS (p/mL)
F0	**Initial**	**7.9E+12**	**9.3E+09**	**1200**	**5.0E+12**	**1.0E+13**	**7.8 E+12**
	3 days	ND	ND	ND	ND	ND	6.3E+12
	1 week	ND	ND	ND	ND	ND	5.4E+12
	2 weeks	ND	ND	ND	ND	ND	3.2E+12
	1 month	**8.1E+12**	**1.7E+07**	**440000**	**4.5E+12**	**5.9E+12**	**4.0 E+12**
	2 months	4.5E+12	ND	ND	3.2E+12	3.9E+12	5.1E+13
	3 months	ND	ND	ND	3.6E+12	4.4E+12	5.2E+12
	7 months	ND	ND	ND	ND	ND	1.2E+13
F1	**Initial**	**8.3E+12**	**9.3E+09**	**1100**	**2.6E+12**	**9.5E+12**	**6.4E+12**
	3 days	ND	ND	ND	ND	ND	ND
	1 week	ND	ND	ND	ND	ND	ND
	2 weeks	ND	ND	ND	ND	ND	ND
	1 month	**3.8E+12**	**1.1E+07**	**280000**	**2.6E+12**	**4.2E+12**	**1.0E+13**
	2 months	5.7E+12	ND	ND	2.5E+12	4.2E+l2	8.6E+12
	3 months	ND	ND	ND	2.4E+12	6.6E+12	1.8E+13
	7 months	ND	ND	ND	ND	ND	1.0E+14
F2	**Initial**	**9.4E+12**	**1.1E+10**	**1100**	**5.2E+12**	**9.9E+12**	**7.3E+12**
	3 days	ND	ND	ND	ND	ND	9.2E+12
	1 week	ND	ND	ND	ND	ND	1.5E+13
	2 weeks	ND	ND	ND	ND	ND	1.5E+13
	1 month	**7.8E+12**	**1.4E+07**	**410000**	**3.4E+12**	**4.9E+12**	**1.4E+13**
	2 months	6.0E+12	ND	ND	2.9E+12	5.9E+12	2.2E+13
	3 months	ND	ND	ND	3.4E+12	9.0E+12	3.2E+13
	7 months	ND	ND	ND	ND	ND	1.0E+13
F3	**Initial**	**7.7E+12**	**1.1E+09**	**8400**	**6.7E+12**	**9.7E+12**	**8.2E+12**
	3 days	ND	ND	ND	ND	ND	6.8E+12
	1 week	ND	ND	ND	ND	ND	2.8E+13
	2 weeks	ND	ND	ND	ND	ND	1.5E+13
	1 month	**8.7E+12**	**2.0E+08**	**42000**	**4.9E+12**	**6.2E+12**	**5.5E+12**
	2 months	9.3E+12	ND	ND	2.7E+12	7.2E+12	8.0E+12

Formulation	Condition	VG Titer (vg/mL)	Infectious Titer ($TCID_{50}$/mL)	VG/$TCID_{50}$	Capsid Titer (capsids/mL)	Monomer Conc. SE-LC, (p/mL)	Monomer Conc. (MADLS (p/mL)
	3 months	ND	ND	ND	2.8E+12	9.4E+12	1.3E+13
	7 months	ND	ND	ND	ND	ND	1.1E+13

FIG. 6D (cont'd)

Quality Attribute	Testing Method	Method Variability	Stability Acceptance Criteria	Failure Criteria
Appearance Liquid	Visual inspection	N/A	Clear colorless, free of particulates	Hazy, cloudy, or visual detection of particles
pH	Potentiometric	± 0.1	7. 1 - 7.5	< 7.1 or > 7.5
Monomer Peak Mean Size	DLS	< 10%	< 10% change from initial (t_0)	> +25% change from initial
Polydispersity Index	DLS	< 10%	PDI < 0.20	PDI > 0.25
Monomer Fraction	DLS	< 2.5%	> 97.5% monomer	< 95% monomer
HMWS Fraction	DLS	< 2.5%	< 2.5% HMWS	> 5% HMWS
HMWS Fraction	SE-LC	< 10%	< 5% HMWS	> 10% HMWS
% Full Capsids	AEX-LC	< 10%	> 85% full capsids	< 80% full capsids
Vector Genome Titer	qPCR	36.0%	-36% to +36% change from initial	< -50% change from initial
Infectious Titer	$TCID_{50}$	50.0%	-50% to +50% change from initial	< -60% change from initial
VG/$TCID_{50}$ Ratio	Calculation	86.0%	-0.5 to +0.5 -$\log_{10}$ change from initial	< - 1 -$\log_{10}$ change from initial
Capsid Concentration	ELISA	20.0%	-20% to +20% change from initial	< -40% change from initial
Monomer Concentration	SE-LC	30.0%	-30% to +30% change from initial	< -40% change from initial
Monomer Concentration	MADLS	< 30%	-25% to +25% change from initial	< -40% change from initial

FIG. 7

Test		Appearance, Liquid	pH	Monomer Peak Mean Size	Polydisp Index	Monomer Fraction, DLS	HMWS Fraction, DLS	HMWS Fraction, SE-LC	% Full Capsids, AEX-LC
Form	*Condition*	*Pass/Fail*	*pH*	*% change from t0*	*PDI*	*% Monomer*	*% HMWS*	*% HMWS*	*% Full*
F0	Initial	Pass	7.3	29.65	0.07	100.0%	0.0%	0.2%	89.2%
	10x F/T	Fail	7.3	1.8%	0.07	99.6%	0.4%	0.0%	89.3%
	3 mo 25°C / 60%RH	Pass	7.4	11.1%	0.13	99.6%	0.4%	0.0%	NAA
	1 mo 40°C / 75%RH	Pass	7.3	12.6%	0.14	100.0%	0.0%	5.4%	NAA
	Assessment	**Fail**	**Pass**	**Neutral**		**Pass**		**Neutral**	**Pass**
F1	Initial	Pass	7.3	33.0	0.12	100.0%	0.0%	0.5%	89.1%
	10x F/T	Pass	7.3	1.0%	0.12	100.0%	0.0%	0.6%	89.2%
	3 mo 25°C / 60%RH	Pass	7.2	10.3%	0.17	100.0%	0.0%	5.5%	NAA
	1 mo 40°C / 75%RH	Pass	7.2	32.9%	0.25	85.5%	14.5%	15.2%	NAA
	Assessment	**Pass**	**Pass**	**Fail**		**Fail**		**Fail**	**Pass**
F2	Initial	Pass	7.2	33.6	0.14	100.0%	0.0%	0.5%	89.3%
	10x F/T	Pass	7.2	0.0%	0.13	100.0%	0.0%	0.5%	89.3%
	3 mo 25°C / 60%RH	Pass	7.2	5.4%	0.17	98.4%	1.6%	1.3%	NAA
	1 mo 40°C / 75%RH	Pass	7.2	23.0%	0.23	99.7%	0.4%	6.5%	NAA
	Assessment	**Pass**	**Pass**	**Neutral**		**Pass**		**Neutral**	**Pass**
F3	Initial	Pass	7.2	33.4	0.12	100.0%	0.0%	0.4%	89.1%
	10x F/T	Pass	7.3	1.0%	0.13	99.5%	0.5%	0.3%	89.0%
	3 mo 25°C / 60%RH	Pass	7.4	3.8%	0.17	100.0%	0.0%	1.7%	NAA
	1 mo 40°C / 75%RH	Pass	7.2	12.9%	0.18	100.0%	0.0%	3.5%	NAA
	Assessment	**Pass**	**Pass**	**Neutral**		**Pass**		**Pass**	**Pass**

FIG. 8

Test		VG Titer, qPCR	Infect Titer, TCID50	VG / TCID50 Ratio	Capsid Conc, ELISA	Monomer Conc, SE-LC	Monomer Conc, MADLS
Form	*Condition*	*% change from t0*	*% change from t0*	*Neg. log change from t0*	*% change from t0*	*% change from t0*	*% change from t0*
F0	Initial	7.9E+12	9.3E+09	1200	5.0E+12	1.0E+13	7.8E+12
	10x F/T	25.1%	0.0%	0.23	24.5%	-13.3%	10.8%
	3 mo 25°C / 60%RH	16.9%	-73.9%	0.02	6.6%	-14.8%	32.0%
	1 mo 40°C / 75%RH	3.2%	-99.8%	-2.57	-9.6%	-40.7%	-43.3%*
	Assessment	**Pass**	**No Score**		**Pass**	**Neutral**	**Neutral**
F1	Initial	8.3E+12	9.3E+09	1100	5.5E+12	9.5E+12	6.4E+12
	10x F/T	36.5%	216.2%	0.54	4.2%	0.2%	-5.5%
	3 mo 25°C / 60%RH	31.4%	-68.3%	0.26	13.6%	-8.5%	-4.6%
	1 mo 40°C / 75%RH	-54.5%	-99.9%	-2.39	-52.1%	-55.5%	28.9%*
	Assessment	**Fail**	**No Score**		**Neutral**	**Neutral**	**Neutral**
F2	Initial	9.4E+12	1.1E+10	1100	5.2E+12	9.9E+12	7.3E+12
	10x F/T	27.3%	115.4%	0.46	7.7%	5.1%	-17.5%
	3 mo 25°C / 60%RH	-13.2%	-68.4%	-0.05	15.8%	6.8%	11.4%
	1 mo 40°C / 75%RH	-17.6%	-99.9%	-2.56	-34.4%	-50.7%	65.9%*
	Assessment	**Pass**	**No Score**		**Pass**	**Neutral**	**Neutral**
F3	Initial	7.7E+12	1.1E+09	8400	6.7E+12	9.7E+12	7.7E+12
	10x F/T	68.9%	216.2%	0.5	-15.2%	3.7%	-23.6%
	3 mo 25°C / 60%RH	22.8%	462.3%	1.27	2.6%	-1.5%	-15.0%
	1 mo 40°C / 75%RH	12.6%	-82.2%	-0.7	-27.0%	-36.1%	0.1%*
	Assessment	**Neutral**	**No Score**		**Pass**	**Pass**	**Pass**

* Result was not reproducible and not considered for final scoring

FIG. 9

Stability Results

Test		Temp (°C)	T0	1 month	3 months	6 months	9 months	12 months	18 months	24 months
Appearance, Liquid	Color	-70	Clear	≤B9	≤B9	≤B9	≤B9	≤B9	≤B9	≤B9
		5		≤B9	≤B9	≤B9		≤B9		
		25		≤B9	≤B9					
	Clarity	-70	Colorless	≤Ref I	≤Ref I	≤Ref I	≤Ref I	≤Ref I	≤Ref I	≤Ref I
		5		≤Ref I	≤Ref I	≤Ref I		≤Ref I		
		25		≤Ref I	≤Ref I					
	Visible Particles	-70	No visible particulates	EFVP	EFVP	EFVP	EFVP	EFVP	EFVP	EFVP
		5		EFVP	EFVP	EFVP		1-5 prtcl*		
		25		EFVP	EFVP					
Container Closure Integrity		-70							Pass	
pH		-70	7.4	7.5	7.4	7.4	7.4	7.4	7.3	7.3
		5		7.4	7.3	7.3		7.4		
		25		7.4	7.3					
Genome Titer (qPCR)		-70	1.06E+13	8.12E+12	9.17E+12	7.45E+12	1.14E+13	8.77E+12	9.05E+12	7.41E+12
		5		7.69E+12	8.93E+12	6.79E+12		9.00E+12		
		25		7.93E+12	9.26E+12					
Capsid Titer (ELISA)		-70	1.50E+13	1.05E+13	1.28E+13	1.07E+13	1.21E+13	1.40E+13	1.59E+13	1.07E+13
		5		1.14E+13	1.26E+13	1.14E+13		1.26E+13		
		25		1.06E+13	1.23E+13					
Infectious Titer ($TCID_{50}$)		-70	4.31E+09	2.93E+09	2.20E+09	9.29E+08	3.56E+09	1.82E+09	2.00E+09	7.67E+09
		5		2.00E+09	9.27E+08	1.36E+09		5.22E+09		
		25		5.22E+09	1.12E+09					
Genome Titer / Infectious Titer Ratio		-70	2459	3618	4818	11410	2978	5824	5300	1382
Capsid Protein Purity (CE): % Capsid		-70	94.8	94.4	94.5	94.5	94.7	94.6	94.5	94.9
		5		94.2	94.8	94.5		94.8		
		25		94.3	93.5					
Capsid Protein Purity (CE): % Other		-70	NR	5.6	5.5	5.5	5.3	5.4	5.5	5.1
		5		5.8	5.2	5.5		5.2		
		25		5.7	6.5					

FIG. 10

Test	Temp (°C)	T0	1 month	3 months	6 months	9 months	12 months	18 months	24 months
Size Distribution (SEC): % Monomer	-70	99.4	98.9	98.9	99.2	99.0	99.3	99.2	99.0
	5		99.1	98.8	99.3		99.1		
	25		98.5	98.5					
Size Distribution (SEC): % Aggregates	-70	NMT 1.0	1.1	1.1	NMT 1.0	1.0	N/A	NMT 1.0	NMT 1.0
	5		NMT 1.0	1.2	NMT 1.0		NMT 1.0		
	25		1.5	1.5					
Particle Content (SEC): 260/280 Ratio	-70	1.32	1.32	1.32	1.32	1.32	1.32	1.33	1.32
	5		1.32	1.32	1.32		1.32		
	25		1.32	1.33					
In vitro FVIII Activity/ Functional Bioassay (% Relative Potency)	-70	73	76	82	64	60	69	60	55
	5		73	60	60		48		
	25		61	42					
P188 Concentration	-70	NT	443.8	454.4	456.8	432.3	464.2	504.8	399.0
	5		NT	467.2	455.7		466.6		
	25		454.7	461.9					

*1-5 particles (prtcl); particle description – "1 long fiber particle"
NR: Not reported, NTM: Not more than, NT: not tested

FIG. 10 (cont'd)