Figure 1

API							
MOR202	50 g/L	50 g/L	50 g/L	75g/L	75g/L	75 g/L	75g/L
Excipients							
Citric Acid Anhydrous	0.450 g/L	0.323g/L	0.203g/L	0.323g/L	0.323g/L		
Sodium Citrate Dihydrate	2.252 g/L	2.447g/L	2.631g/L	2.447g/L	2.447g/L		
NaCl					3.0g/L		
L-Histidine						1.552 g/L	1.552g/L
HCl						q.s. to pH 6.0±0.1	q.s. to pH 5.5±0.1
pH	5.7±0.1	6.0±0.1	6.3±0.1	6.0±0.1	6.0±0.1	6.0±0.1	5.5±0.1

Figure 2

Test	Method	Storage Condition	Timepoint		
			0 week	2 week	4 week
Appearance	Visual	5°C	X		X
		25°C			
		40°C		X	X
Particle Count	HIAC	5°C	X		X
		25°C			
		40°C		X	X
Particle Size	DLS	5°C	X		X
		25°C			
		40°C		X	X
Purity	SEC	5°C	X		X
		25°C			
		40°C		X	X
Protein Content	UV	5°C	X		X
		25°C			
		40°C		X	X
pH	pH meter	5°C	X		X
		25°C			
		40°C		X	X

Figure 3A

Time 0		10mM Buffer			
		n.a.	50g/L MOR202		
		L-Histidine pH 6.0	Citrate pH 5.7	Citrate pH 6.0	Citrate pH 6.3
Appearance		Clear colourless solution. Few visible particles	Slightly opalescent slightly yellow. Few visible particles	Slightly opalescent slightly yellow. Few visible particles	Slightly opalescent slightly yellow. Few visible particles
UV280nm (mg/mL)		n.a.	66.5	70.9	69.5
pH		6.0	5.6	5.9	6.2
DLS	Intensity ø (nm)	11.1	27.9	31.3	40.7
	Volume ø (nm):	10.9	21.5	23.8	31.2
	Number ø (nm):	10.7	18.1	18.0	23.8
	P.I.	0.281	0.057	0.092	0.090
SEC	%IgG	n.a.	96.36	95.99	95.56
	%aggregates	n.a.	3.46	3.84	4.26
	%contaminants	n.a.	0.18	0.17	0.18
HIAC (particles/ mL)	2 µm	70	1515	718	8354
	5 µm	6	172	76	663
	10 µm	0	30	7	43
	20 µm	0	3	0	6
	25 µm	0	0	0	3
	50 µm	0	0	0	2

Figure 3B

Time 0		10mM Buffer			
		75g/L MOR202			
		Citrate pH 6.0	L-Histidine pH 6.0	Citrate+0.3%NaCl pH 6.0	L-Histidine pH 5.5
Appearance		Slightly opalescent slightly yellow. Few visible particles	Clear, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Clear, slightly yellow. Few visible particles
UV280nm (mg/mL)		94.6	78.9	76.2	76.6
pH		5.8	6.2	6.0	5.7
DLS	Intensity ø (nm)	39.1	11.1	35.1	11.1
	Volume ø (nm):	29.5	10.9	27.0	10.9
	Number ø (nm):	22.2	10.7	20.8	10.7
	P.I.	0.094	0.397	0.087	0.506
SEC	%IgG	95.97	97.16	96.85	97.54
	%aggregates	3.86	2.88	3.06	2.37
	%contaminants	0.17	0.15	0.09	0.08
HIAC (particles/mL)	2 µm	3428	107	775	1052
	5 µm	424	10	26	190
	10 µm	39	0	2	23
	20 µm	3	0	0	2
	25 µm	2	0	0	0
	50 µm	0	0	0	0

Figure 3C

2 wks 40 °C / 75% RH		10mM Buffer			
		n.a.	50g/L MOR202		
		L-Histidine pH 6.0	Citrate pH 5.7	Citrate pH 6.0	Citrate pH 6.3
Appearance		Clear colourless solution. Few visible particles	Slightly opalescent slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles
UV280nm (mg/mL)		n.a.	66.4	70.1	69.2
pH		6.1	5.7	5.9	6.2
DLS	Intensity ø (nm)	11.4	28.1	34.5	42.7
	Volume ø (nm):	11	11.7	20.6	24.8
	Number ø (nm):	10.8	18.2	12.2	14.2
	P.I.	0.281	0.146	0.173	0.183
SEC	%IgG	n.a.	94.44	93.61	92.88
	%aggregates	n.a.	5.21	6.06	6.79
	%contaminants	n.a.	0.34	0.33	0.32
HIAC (particles/ mL)	2 µm	26	2656	4872	4355
	5 µm	4	303	604	535
	10 µm	0	31	75	71
	20 µm	0	0	4	8
	25 µm	0	0	0	6
	50 µm	0	0	0	2

Figure 3D

2 wks 40 °C / 75% RH		10mM Buffer 75g/L MOR202			
		Citrate pH 6.0	**L-Histidine pH 6.0**	**Citrate+0.3%NaCl pH 6.0**	**L-Histidine pH 5.5**
Appearance		Opalescent, slightly yellow. Few visible particles	Slightly opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles
UV280nm (mg/mL)		94.2	77	79.6	82.6
pH		5.9	6.3	6.3	5.9
DLS	**Intensity ø (nm)**	40.4	11.2	Peack#1: 26.1 Peack#2: 58.1	16.8
	Volume ø (nm):	27.8	10.9	Peack#1: 23.9 Peack#2: 110.2	5.8
	Number ø (nm):	19	10.7	Peack#1: 22.8 Peack#2: 52.2 Peack#3: 107.8	2.7
	P.I.	0.125	0.376	0.229	0.366
SEC	**%IgG**	93.38	94.29	97.33	95.16
	%aggregates	6.31	5.23	2.58	4.31
	%contaminants	0.32	0.48	0.09	0.53
HIAC (particles/mL)	**2 µm**	2296	3850	12874	27982
	5 µm	272	295	1559	6618
	10 µm	58	28	55	547
	20 µm	6	0	4	23
	25 µm	2	0	2	6
	50 µm	0	0	0	2

Figure 3E

4 wks 40 °C / 75% RH		10mM Buffer					
		n.a.	50g/L MOR202			75g/L MOR202	
		L-Histidine pH 6.0	Citrate pH 5.7	Citrate pH 6.0	Citrate pH 6.3	Citrate pH 6.0	L-Histidine pH 6.0
Appearance		Clear colourless solution with few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Slightly opalescent, slightly yellow. Few visible particles
UV280nm (mg/mL)		n.a.	69.1	72.8	73.1	100.0	80.0
pH		6.1	5.6	5.9	6.2	5.9	6.2
DLS	Intensity ø (nm)	11.2	28.7	37.3	45.2	42.1	11.2
	Volume ø (nm):	10.9	17.5	22	22.3	25.4	10.9
	Number ø (nm):	10.7	10.6	12.9	11.2	15.2	10.7
	P.I.	0.356	0.165	0.176	0.238	0.17	0.291
SEC	%IgG	n.a.	93.15	92.61	91.63	91.76	92.5
	%aggregates	n.a.	6.27	6.71	7.82	7.72	6.86
	%contaminants	n.a.	0.58	0.68	0.55	0.52	0.63
HIAC (particles/mL)	2 µm	118	1939	1563	7412	4448	798
	5 µm	18	152	171	1052	527	87
	10 µm	0	12	15	195	59	15
	20 µm	0	0	2	4	2	3
	25 µm	0	0	2	0	0	3
	50 µm	0	0	0	0	0	0

Figure 3F

2 wks 5 °C		10mM Buffer 75g/L MOR202	
		Citrate+0.3%NaCl pH 6.0	**L-Histidine pH 5.5**
Appearance		Opalescent, slightly yellow, with few visible particles	Clear, slightly yellow, with few visible particles
UV280nm (mg/mL)		79.3	80.3
pH		6.0	5.6
DLS	**Intensity ø (nm)**	35.7	2510.5
	Volume ø (nm):	27.8	5458.6
	Number ø (nm):	21.6	647.3
	P.I.	0.084	0.908
SEC	**%IgG**	96.28	93.44
	%aggregates	3.62	6.24
	%contaminants	0.09	0.32
HIAC (particles/ mL)	**2 µm**	1475	215
	5 µm	114	42
	10 µm	15	6
	20 µm	0	0
	25 µm	0	0
	50 µm	0	0

Figure 3G

4 wks 5 °C		10mM Buffer					
		n.a.	50g/L MOR202			75g/L MOR202	
		L-Histidine pH 6.0	Citrate pH 5.7	Citrate pH 6.0	Citrate pH 6.3	Citrate pH 6.0	L-Histidine pH 6.0
Appearance		Clear colourless solution. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Opalescent, slightly yellow. Few visible particles	Slightly opalescent, slightly yellow. Few visible
UV280nm (mg/mL)		n.a.	68.8	73.1	71.3	98.4	77.8
pH		6.1	5.6	5.9	6.2	5.9	6.2
DLS	Intensity ø (nm)	11.2	25.6	31.1	37.8	39	11.1
	Volume ø (nm):	10.9	19.7	23.5	28.5	29.1	10.9
	Number ø (nm):	10.7	15.5	17.7	21.4	21.7	10.7
	P.I.	0.726	0.084	0.094	0.095	0.098	0.227
SEC	%IgG	n.a.	96.38	95.86	95.27	95.67	96.82
	%aggregates	n.a.	3.53	4.05	4.65	4.24	3.09
	%contaminants	n.a.	0.09	0.09	0.09	0.09	0.10
HIAC (particles/mL)	2 µm	74	2487	2235	3288	2232	704
	5 µm	15	384	323	555	279	68
	10 µm	2	48	40	75	32	6
	20 µm	0	3	3	2	4	3
	25 µm	0	2	2	0	3	3
	50 µm	0	0	0	0	0	0

Figure 4A

Shear test		T0		
		PS20 0.02%	PS20 0.04%	PS20 0.1%
Physical Appearance		Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles
UV Abs 280 nm (mg/mL)		76.6	75.9	75.0
DLS Diameter (nm)	Intensity:	11.3±0.6	11.2 ±0.6	11.1 ±0.6
	Volume:	3.5±0.6	3.4±0.6	3.4±0.6
	Number:	1.7±0.6	1.7±0.6	1.7±0.6
	P.I.	0.40	0.41	0.42
SEC	%IgG	97.38	97.38	97.37
	%aggragates	2.56	2.55	2.56
	%contaminants	0.07	0.07	0.07

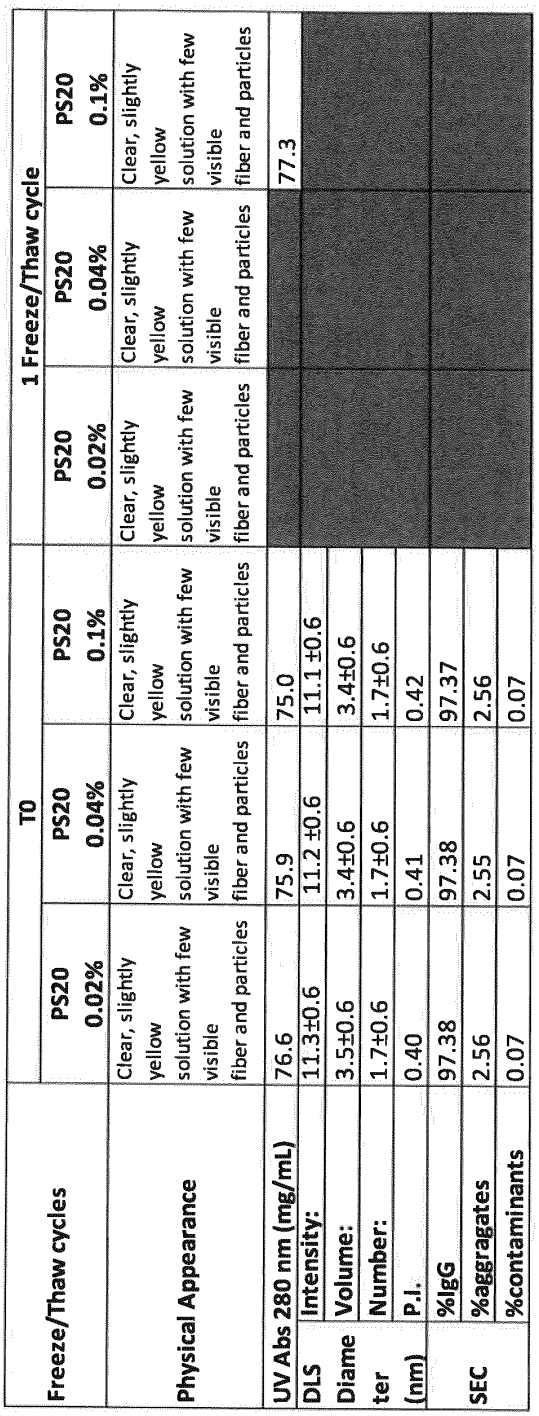
Figure 4B

Shear test		T24h shear		
		PS20 0.02%	PS20 0.04%	PS20 0.1%
Physical Appearance		Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles
UV Abs 280 nm (mg/mL)				
DLS Diameter (nm)	Intensity:			
	Volume:			
	Number:			
	P.I.			
SEC	%IgG			
	%aggragates			
	%contaminants			

Figure 4C

Shear test		T48h shear		
		PS20 0.02%	**PS20 0.04%**	**PS20 0.1%**
Physical Appearance		Slightly opalescent, slightly yellow solution. Few visible fibers and particles. The opalescence is slightly higher than other compositions.	Slightly opalescent, slightly yellow solution with few visible fiber and particles.	Slightly opalescent, slightly yellow solution with few visible fiber and particles.
UV Abs 280 nm (mg/mL)		74.7	78.0	73.4
DLS Diameter (nm)	**Intensity:**	12.3 ±0.7	12.5 ±0.7	12.5 ±0.7
	Volume:	3.6±0.7	3.6±0.7	3.4±0.7
	Number:	1.8±0.7	10.7±0.7	10.7±0.7
	P.I.	0.43	0.45	0.47
SEC	**%IgG**	96.92	96.90	96.84
	%aggragates	2.98	3.00	3.05
	%contaminants	0.11	0.11	0.11

Figure 4D



Freeze/Thaw cycles		T0			1 Freeze/Thaw cycle		
		PS20 0.02%	PS20 0.04%	PS20 0.1%	PS20 0.02%	PS20 0.04%	PS20 0.1%
Physical Appearance		Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles
UV Abs 280 nm (mg/mL)		76.6	75.9	75.0			77.3
DLS	Intensity:	11.3±0.6	11.2 ±0.6	11.1 ±0.6			
Diame	Volume:	3.5±0.6	3.4±0.6	3.4±0.6			
ter	Number:	1.7±0.6	1.7±0.6	1.7±0.6			
(nm)	P.I.	0.40	0.41	0.42			
SEC	%IgG	97.38	97.38	97.37			
	%aggragates	2.56	2.55	2.56			
	%contaminants	0.07	0.07	0.07			

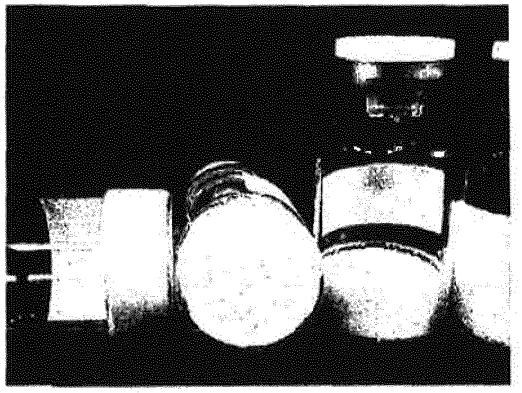
Figure 4E

Freeze/Thaw cycles		2 Freeze/Thaw cycle			3 Freeze/Thaw cycle		
		PS20 0.02%	PS20 0.04%	PS20 0.1%	PS20 0.02%	PS20 0.04%	PS20 0.1%
Physical Appearance		Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles	Clear, slightly yellow solution with few visible fiber and particles
UV Abs 280 nm (mg/mL)				76.9	77.4	76.8	76.9
DLS Diameter (nm)	Intensity:				3.5±0.6	11.2±0.6	11.1±0.6
	Volume:				1.7±0.6	3.4±0.6	3.4±0.6
	Number:				1.7±0.6	1.7±0.6	1.7±0.6
	P.I.				0.42	0.41	0.41
SEC	%IgG				97.07	97.05	97.02
	%aggragates				2.84	2.86	2.88
	%contaminants				0.09	0.09	0.10

Figure 4F

Saline dilution		T0			T24h		
		PS20 0.02%	PS20 0.04%	PS20 0.1%	PS20 0.02%	PS20 0.04%	PS20 0.1%
SEC	%IgG	97.39	97.36	97.37	97.53	97.53	97.45
	%aggragates	2.52	2.54	2.54	2.38	2.38	2.41
	%contaminants	0.09	0.09	0.09	0.09	0.09	0.14
Particle count (p/mL)	2 µm	5148	2283	2256	10592	8272	4244
	5 µm	924	410	347	2518	1779	766
	10 µm	144	71	46	384	221	110
	20 µm	8	6	3	20	10	10
	25 µm	8	2	2	7	3	2
	50 µm	0	0	2	0	0	0

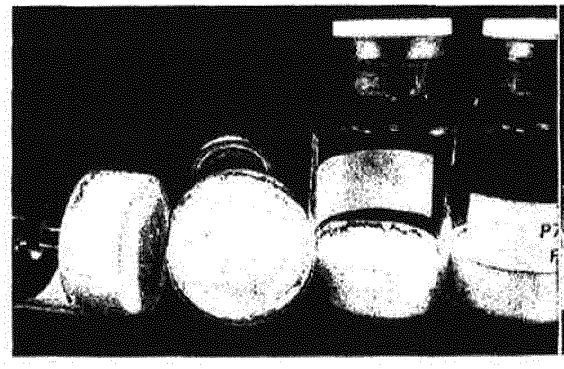
Figure 5



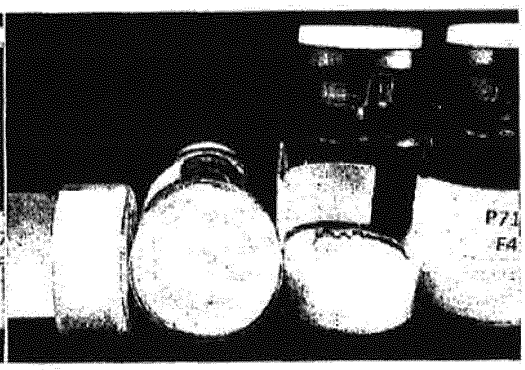
F1 vials



F2 vials



F3 vials



F4 vials

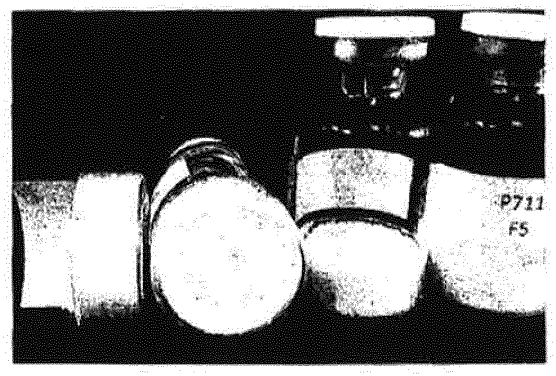


Figure 6A

Test	Time 0					2wks 40°C				
	F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
Appearance of solution	O: II C: Y- P: ø	O: II C: Y- P: ø	O: I C: Y- P: ø	O: III C: ø P: ø	O: III C: ø P: ø	O: III C: Y- P: ø	O: IV C: Y- P: ø	O: I C: Y- P: ø	O: II C: ø P: ø	O: III C: ø P: ø
UV assay (mg/mL)	62.8	62.8	62.3	63.8	63.5	64.7	59.9	63.8	65.1	63.2

Appearance of solution:

O = opalescence
I: comparable to reference standard of opalescence I
II: comparable to reference standard of opalescence II
III: comparable to reference standard of opalescence III
IV: comparable to reference standard of opalescence IV

C = colour
Y-: slightly yellow
Y:yellow
ø: Colourless

P: visible particles
ø: free of visible particles

Figure 6B

Test	4wks 40°C/75 %RH					4wks 5°C				
	F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
Appearance of solution	O: IV C: Y P: ø	O: IV C: Y- P: ø	O: II C: Y P: ø	O: IV C: Y- P: ø	O: IV C: Y- P: ø	O: II C: Y- P: ø	O: III C: Y- P: ø	O: II C: Y- P: ø	O: IV C: Y- P: ø	O: IV C: Y- P: ø
UV assay (mg/mL)	61.6	56.9	61.7	60.2	58.5	63.1	62.0	62.8	64.3	63.1

Appearance of solution:

O = opalescence
I: comparable to reference standard of opalescence I
II: comparable to reference standard of opalescence II
III: comparable to reference standard of opalescence III
IV: comparable to reference standard of opalescence IV

C = colour
Y-: slightly yellow
Y:yellow
ø: Colourless

P: visible particles
ø: free of visible particles

Figure 6C

Test	4wks 25°C/60%RH				
	F1	F2	F3	F4	F5
Appearance of solution	O: III C: Y- P: ø	O: III C: Y- P: ø	O: I C: Y- P: ø	O: III C: Y- P: ø	O: IV C: Y- P: ø
UV assay (mg/mL)	63.1	62.4	62.3	63.6	62.5

Appearance of solution:

O = opalescence
I: comparable to reference standard of opalescence I
II: comparable to reference standard of opalescence II
III: comparable to reference standard of opalescence III
IV: comparable to reference standard of opalescence IV

C = colour
Y-: slightly yellow
Y:yellow
ø: Colourless

P: visible particles
ø: free of visible particles

Figure 6D

Test		Time 0					2wks 40°C				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
pH		6.1	6.1	6.1	6.2	6.1	6.0	6.1	6.2	6	6.1
SE-HPLC	% Monomer	95.84	95.81	95.8	95.77	95.71	90.12	89.47	90.70	93.98	90.46
	%HMW	3.80	3.80	3.86	3.87	3.94	8.81	9.35	8.42	5.24	8.82
	%LMW	0.36	0.38	0.34	0.36	0.36	1.07	1.18	0.88	0.78	0.93

Test		4wks 40°C/75 %RH					4wks 5°C				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
pH		6.0	6.0	6.0	6.1	6.00	6.1	6.1	6.1	6.1	6.1
SE-HPLC	% Monomer	77.58	77.91	79.68	81.41	84.22	95.7	95.7	95.61	95.62	95.51
	%HMW	16.00	16.75	13.93	13.07	9.77	3.85	3.84	3.93	3.93	4.05
	%LMW	6.42	5.34	6.39	5.52	6.01	0.46	0.45	0.46	0.45	0.45

Test		4wks 25°C/60%RH				
		F1	F2	F3	F4	F5
pH		6.1	6.0	6.1	6.1	6.1
SE-HPLC	% Monomer	95.37	95.02	95.21	95.24	95.04
	%HMW	4.12	4.37	4.28	4.28	4.48
	%LMW	0.05	0.06	0.01	0.05	0.05

Figure 6E

Test*		Time 0					2wks 40°C				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
DLS	Intensity: Diameter (nm)	15.0 ± 4.2	22.9 ± 2.9	11.1 ± 1.2	25.0 ± 3.1	#1= 11.3 ± 1.0 #2= 28.3 ± 3.0	#1= 11.7 ± 1.0 #2= 247.2 ± 25.8	#1= 18.5 ± 1.0 #2= 89.6 ± 10.1	11.2 ± 1.0	27.0 ± 2.7	#1= 11.4 ± 0.9 #2= 32.3 ± 6.5 #3= 182.2 ± 11.8
	Volume: Diameter (nm)	11.8 ± 3.3	10.9 ± 1.0	10.9 ± 0.8	22.9 ± 2.8	#1= 11.1 ± 0.8 #2= 26.7 ± 3.3	#1= 11.6 ± 1.0 #2= 243.4 ± 12.9	#1= 17.2 ± 2.5 #2= 83.6 ± 11.3	10.9 ± 0.7	25.9 ± 3.5	#1= 11.2 ± 1.0 #2= 28.4 ± 5.8 #3= 180.2 ± 7.2
	Number: Diameter (nm)	10.9 ± 0.7	11.0 ± 0.7	10.7 ± 0.8	Peak#1 = 10.9 ± 0.8 Peak#2 = 21.6 ± 3.1	#1= 10.8 ± 0.7 #2= 25.8 ± 3.6	11.0 ± 0.9	#1= 16.5 ± 1.9 #2= 80.1 ± 8.1	10.7 ± 0.8	#1= 10.9 ± 0.8 #2= 24.8 ± 2.6	#1= 10.9 ± 0.7 #2= 27.8 ± 4.3

Figure 6F

Test*		4wks 40°C/75 %RH					4wks 5°C				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
DLS	Intensity: Diameter (nm)	11.7 ± 1.0	#1= 11.3 ± 1.0 #2= 37.1 ± 3.5 #3= 134.5 ± 14.9	#1= 11.2 ± 1.0 #2= 97.6 ± 3.4	#1= 11.6 ± 0.9 #2= 22.8 ± 2.4 #3= 110.8 ± 13.4	#1= 19.1 ± 2.4 #2= 99.4 ± 11.1	12.8 ± 2.5	22.9 ± 2.7	11.1 ± 1.2	25.0 ± 3.1	26.9 ± 3.3
	Volume: Diameter (nm)	11.4 ± 1.2	#1= 11.0 ± 0.7 #2= 35.6 ± 4.6 #3= 126.6 ± 17.0	#1= 11.0 ± 0.7 #2= 134.6 ± 2.3	#1= 20.6 ± 2.5 #2= 103.9 ± 13.2	#1= 18.3 ± 2.1 #2= 93.0 ± 12.4	12.2 ± 1.2	12.6 ± 1.0	10.9 ± 0.7	22.9 ± 2.9	#1= 11.0 ± 0.7 #2= 25.8 ± 3.9
	Number: Diameter (nm)	11.0 ± 0.9	#1= 10.8 ± 0.8 #2= 34.1 ± 3.8 #3= 121.6 ± 2.8	10.8 ± 0.8	#1= 11.1 ± 0.7 #2= 99.6 ± 1.8	#1= 10.9 ± 1.0 #2= 89.3 ± 6.8	#1= 10.9 ± 0.7 #2= 19.6 ± 1.6	11.0 ± 0.7	10.7 ± 0.8	#1= 10.9 ± 0.8 #2= 21.6 ± 3.0	#1= 10.8 ± 0.8 #2= 24.3 ± 2.8

Figure 6G

Test*		4wks 25°C/60%RH				
		F1	F2	F3	F4	F5
DLS	Intensity: Diameter (nm)	#1= 11.4 ± 0.9 #2= 27.0 ± 1.6 #3= 42.6 ± 1.3	24.9 ± 3.1	11.1 ± 1.2	25.1 ± 3.2	#1= 11.4 ± 0.9 #2= 31.7 ± 5.4
	Volume: Diameter (nm)	#1= 11.2 ± 1.0 #2= 26.8 ± 1.8 #3= 42.4 ± 1.4	17.3 ± 4.7	10.9 ± 0.7	#1= 12.5 ± 2.9 #2= 22.8 ± 3.0	#1= 11.2 ± 1.0 #2= 29.6 ± 4.4
	Number: Diameter (nm)	#1= 10.9 ± 0.7 #2= 26.5 ± 2.6 #3= 42.2 ± 1.6	#1= 10.9 ± 0.8 #2= 21.4 ± 3.2	10.7 ± 0.8	11.0 ± 0.7	#1= 10.9 ± 0.8 #2= 28.1 ± 3.1

Figure 6H

		Time 0					2wks 40°C				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
Sub-visible particles (HIAC)	2 µm	303	278	95	178	543	33996	416	110	259	496
	5 µm	40	56	14	34	16	16596	36	20	54	56
	10 µm	4	22	7	18	8	1708	8	7	10	7
	20 µm	0	4	4	3	3	4	0	2	2	0
	25 µm	0	0	0	2	2	0	0	0	0	0
	50 µm	0	0	0	0	0	0	0	0	0	0

		4wks 40°C/75 %RH					4wks 5°C				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
Sub-visible particles (HIAC)	2 µm	196	80	118	154	159	434	110	18	219	344
	5 µm	59	11	22	30	31	74	32	2	75	55
	10 µm	23	3	8	19	15	22	19	2	34	20
	20 µm	4	2	4	0	4	4	8	0	4	6
	25 µm	3	2	2	0	2	3	2	0	2	3
	50 µm	0	2	0	0	2	0	0	0	0	0

		4wks 25°C/60%RH				
		F1	F2	F3	F4	F5
Sub-visible particles (HIAC)	2 µm	9854	78	48	184	4998
	5 µm	468	15	12	52	18
	10 µm	63	6	6	19	4
	20 µm	18	0	4	2	3
	25 µm	12	0	3	2	0
	50 µm	3	0	0	0	0

Figure 7A

Test	Time 0					2wks 40°C					4wks 40°C/75 %RH				
	F1	F2	F3	F4	F5	F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
Physical Appearance	O: II C: Y- P: ø	O: II C: Y- P: ø	O: I C: Y- P: ø	O: III C: ø P: ø	O: III C: ø P: ø	O: II C: Y- P: ø	O: II C: Y- P: ø	O: I C: Y- P: ø	O: IV C: ø P: ø	O: IV C: ø P: ø	O: II C: Y- P: ø	O: III C: Y- P: ø	O: I C: Y- P: ø	O: IV C: Y- P: ø	O: IV C: Y- P: ø
UV assay (mg/mL)	59.6	60.6	59.1	61.7	62.1	64	62.4	63.0	62.4	63.9	62.5	63.4	60.8	61.5	62.9
pH	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.1	6.2	6.1

Appearance of solution:

O = opalescence I: comparable to reference standard of opalescence I
II: comparable to reference standard of opalescence II
III: comparable to reference standard of opalescence III
IV: comparable to reference standard of opalescence IV

C = colour Y-: slightly yellow
Y: yellow
ø: Colourless

P: visible particles
ø: free of visible particles

Figure 7B

Test*		Time 0				
		F1	F2	F3	F4	F5
DLS	Intensity: Diameter (nm)	18.1 ± 1.4	22.7 ± 2.5	11.1 ± 1.2	24.9 ± 3.1	26.7 ± 3.1
	Volume: Diameter (nm)	#1= 11.2 ± 1.2 #2= 19.4 ± 1.4	12.7 ± 1.0	10.9 ± 0.8	17.3± 4.7	25.5± 2.8
	Number: Diameter (nm)	#1= 10.9 ± 0.8 #2= 19.3 ± 1.6	11.1 ±0.7	10.7 ± 0.8	#1= 10.9 ± 0.8 #2= 21.4 ± 3.2	#1= 10.9 ± 0.8 #2= 24.4 ± 2.9
Appearance of cake		White solid cake	White solid cake	White solid cake	White solid cake	White solid cake
Reconstitution time (min)		1.75	1.92	3.53	2.28	2.05
Moisture content (%W/W)		0.3	0.28	0.24	0.24	0.23

*#1 and #2 corresponds to #1 and #2

Figure 7C

Test*		2wks 40°C				
		F1	F2	F3	F4	F5
DLS	Intensity: Diameter (nm)	#1= 12.7 ± 1.4 #2= 30.1 ± 1.9	22.8 ± 2.7	11.1 ± 1.2	24.9 ± 3.1	#1= 11.3 ± 1.0 #2= 28.2 ± 3.0
	Volume: Diameter (nm)	#1= 12.2 ± 1.2 #2= 29.6 ± 2.2	12.7 ± 1.0	10.9 ± 0.8	22.7 ± 2.8	#1= 11.1 ± 0.8 #2= 26.5 ± 3.4
	Number: Diameter (nm)	#1= 10.9± 0.7 #2= 19.3 ± 1.6 #3= 29.0 ± 2.4	11.1 ± 0.7	10.7 ± 0.8	#1= 10.9 ± 0.8 #2= 21.4 ± 3.1	#1= 10.8 ± 0.7 #2= 25.5 ± 2.5
Appearance of cake		White solid cake	White solid cake	White solid cake	White solid cake	White solid cake
Reconstitution time (min)		2.75	2.55	3.08	2.65	3.05
Moisture content (%W/W)		0.32	0.3	0.37	0.26	0.25

*#1 and #2 corresponds to #1 and #2

Figure 7D

Test*		4wks 40°C/75 %RH				
		F1	F2	F3	F4	F5
DLS	Intensity: Diameter (nm)	#1= 12.7 ± 0.9 #2= 28.2 ± 1.2	23.1 ± 3.8	11.1 ± 1.2	23.7± 3.6	26.4± 3.5
	Volume: Diameter (nm)	#1= 11.7 ± 0.6 #2= 28.0 ± 2.1	12.5 ± 1.0	10.9 ± 0.8	12.4 ± 1.4	#1= 11.0 ± 0.7 #2= 25 2 ± 2.8
	Number: Diameter (nm)	#1= 10.9 ± 0.7 #2= 19.2 ± 1.6 #3= 27.7 ± 1.0	11.0 ± 0.7	10.7 ± 0.8	##1= 10.9 ±0.8 ##2=20.6 ± 2.7	##1= 10.8 ±0.8 ##2=23.8 ± 3.8
Appearance of cake		White solid cake	White solid cake	White solid cake	White solid cake	White solid cake
Reconstitution time (min)		3.70	4.60	4.50	3.63	4.90
Moisture content (%W/W)		0.23	0.23	0.17	0.22	0.25

*#1 and #2 corresponds to #1 and #2

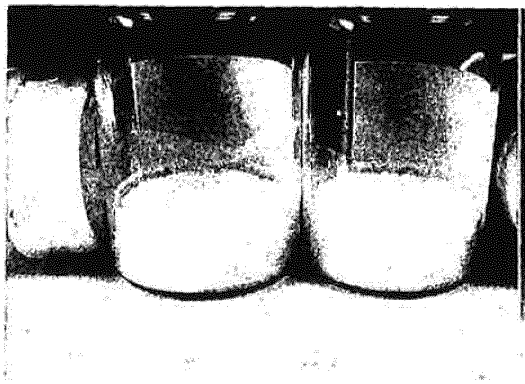
Figure 7E

Test		Time 0					2wks 40°C					4wks 40°C/75 %RH				
		F1	F2	F3	F4	F5	F1	F2	F3	F4	F5	F1	F2	F3	F4	F5
SE-HPLC	%IgG	95.77	95.76	95.78	95.75	95.70	95.54	95.55	95.55	95.56	95.42	95.49	95.51	95.5	95.52	95.32
	%HMW	3.84	3.85	3.85	3.88	3.93	4.02	4.02	4.04	4.02	4.16	4.05	4.05	4.09	4.06	4.23
	%LMW	0.39	0.39	0.36	0.37	0.37	0.44	0.43	0.41	0.42	0.42	0.46	0.44	0.41	0.42	0.44
Sub-visible particles (HIAC)	2 µm	534	856	459	599	928	487	724	428	784	672	176	124	43	170	204
	5 µm	148	136	106	115	180	86	144	94	119	130	26	26	10	14	55
	10 µm	24	20	32	26	19	12	8	26	15	14	4	8	7	4	28
	20 µm	2	3	6	6	6	3	0	4	3	0	0	3	2	3	10
	25 µm	2	0	6	2	3	2	0	0	2	0	0	3	0	0	2
	50 µm	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0

Figure 8

<table>
<tr><td>Test</td><td colspan="4">P711-05</td></tr>
<tr><td>Appearance of the cake</td><td colspan="4">White and cohesive cake</td></tr>
<tr><td>Reconstitution time</td><td colspan="4">435 sec</td></tr>
<tr><td>Appearance of reconstituted solution</td><td colspan="4">Clear, slightly yellow solution and free of visible particles</td></tr>
<tr><td>pH</td><td colspan="4">6.1</td></tr>
<tr><td>Protein content (by UV Assay at 280nm) (mg/mL)</td><td colspan="4">67.7</td></tr>
<tr><td>Moisture content DP lyo(n=3) (%w/w)</td><td colspan="4">sample 1= 0.40
sample 2= 0.51
sample 3=0.49
average=0.47</td></tr>
<tr><td>HIAC</td><td colspan="4">2 µm size = 427 particles/mL
5 µm size = 134 particles/mL
10 µm size = 59 particles/mL
20 µm size= 6 particles/mL
25 µm size = 3 particles/mL
50 µm size = 1 particles/mL</td></tr>
<tr><td>SEC</td><td>Monomer %</td><td colspan="3">97.27</td></tr>
<tr><td></td><td>Total aggregates %</td><td colspan="3">2.32</td></tr>
<tr><td></td><td>Total contaminants %</td><td colspan="3">0.41</td></tr>
<tr><td>Sub visible particles (by DLS)</td><td colspan="4">Gaussian Summary</td></tr>
<tr><td></td><td>Intensity</td><td colspan="3">NA</td></tr>
<tr><td></td><td>Volume</td><td colspan="3">NA</td></tr>
<tr><td></td><td>Number</td><td colspan="3">NA</td></tr>
<tr><td></td><td colspan="4">Nicomp Summary</td></tr>
<tr><td></td><td>Nicomp Summary</td><td>Intensity</td><td>Volume</td><td>Number</td></tr>
<tr><td></td><td>Peak #1 (nm)</td><td>11.1±1.2(100.00%)</td><td>10.9±0.7(100.0%)</td><td>10.7±0.8 (100.0%)</td></tr>
<tr><td></td><td>Peak #2(nm)</td><td>n.a.</td><td>n.a.</td><td>n.a.</td></tr>
<tr><td></td><td>Peak #3 (nm)</td><td>n.a.</td><td>n.a.</td><td>n.a.</td></tr>
</table>

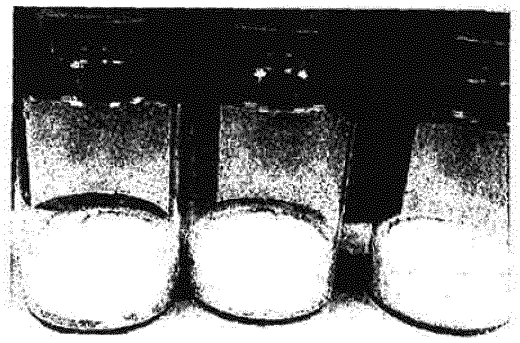
Figure 9



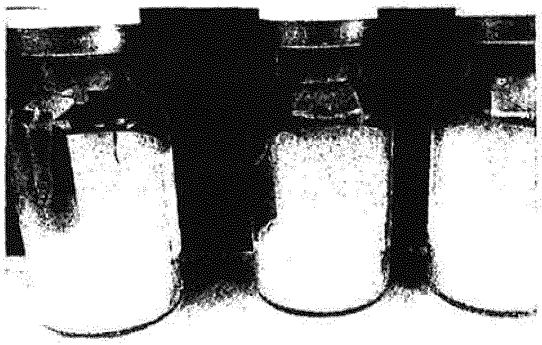
P711-05 conformed vials



P711-05 product on the neck



P711-05 vials with very small presence of product (Microscopic drop) between stopper and neck



P711-05 vials with stains