

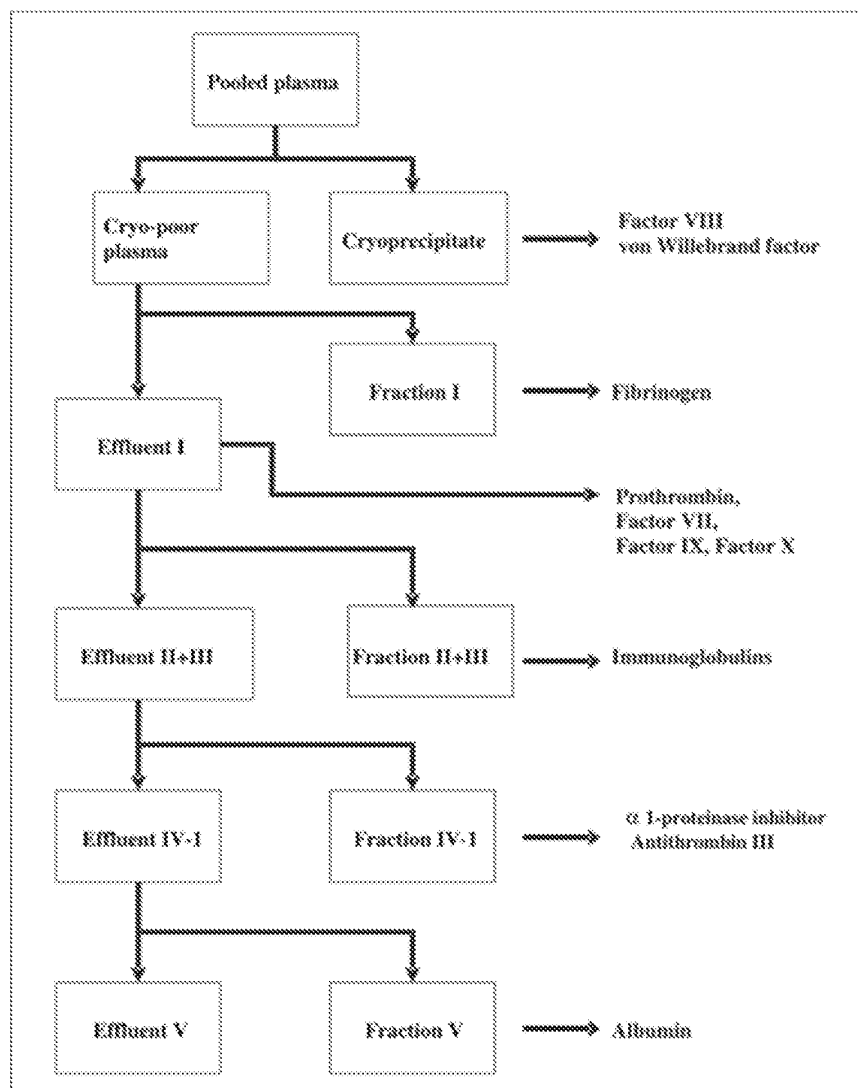


FIGURE 1

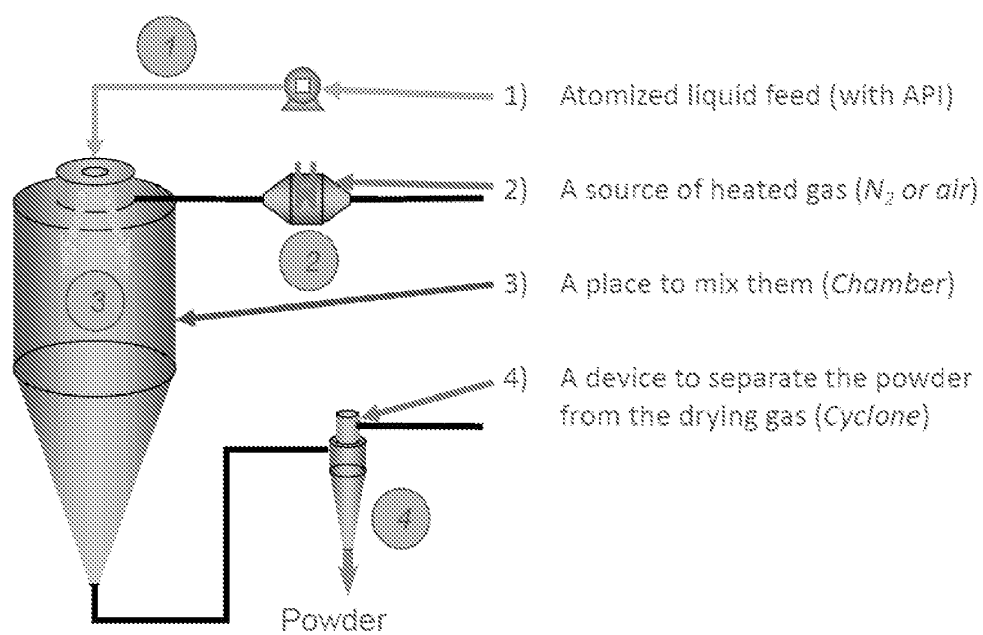


FIGURE 2

Coagulation Factor Activity of Thawed Plasma Derived from FFP*							
Coagulation Factor	Level †					Mean Change from Day 1 to Day 5 (%)	p Values
	Day 1	Day 2	Day 3	Day 4	Day 5		
Factor VIII (%)							
Blood group A	107 ± 26	76 ± 19	66 ± 18	65 ± 17	63 ± 16	41	<0.004 [‡]
Blood group B	103 ± 44	74 ± 37	71 ± 25	67 ± 36	67 ± 33	35	<0.024
Blood group O	70 ± 16	51 ± 10	45 ± 10	45 ± 7	41 ± 8	41	<0.001 [‡]
Factor II (%)	81 ± 9	81 ± 9	81 ± 9	80 ± 10	80 ± 10	1	NS
Factor V (%)	79 ± 7	75 ± 8	71 ± 9	68 ± 9	66 ± 9	16	NS
Factor VII (%)	90 ± 18	81 ± 15	76 ± 15	72 ± 14	72 ± 15	20	NS
Factor X	85 ± 13	84 ± 13	84 ± 15	82 ± 11	80 ± 11	6	NS
Fibrinogen (mg/dL)	225 ± 12	224 ± 13	224 ± 13	224 ± 17	225 ± 12	0	NS

FIGURE 3

A/ PROCESS	DOE settings											Other process equipment setting logged data during processing	DOE responses
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11		
Solid Content (w/w)	6.22%	6.22%	6.22%	6.22%	6.22%	6.22%	6.22%	6.22%	6.22%	6.22%	6.22%		
Total dosed sample (mL)	140	140	140	140	140	140	140	140	140	140	140		
Total dosed sample (g)	139.3	139.82	139.12	142.55	142.58	144.95	140.3	140.04	141.36	139.51	140.85		
Surface water (mL)	7.3	9.5	11.3	15.3	15.3	15.3	9.3	9.3	9.3	9.3	11.4		
Time for 1 st cycle	130	140	140	140	140	140	140	140	140	140	135		
Number of cycles (cycles)	10	10	10	10	10	10	10	10	10	10	10		
Longest cycle (min)	4	4	8	4	8	4	4	4	8	4	4		
Column	extended	extended	extended	extended	extended	extended	extended	extended	extended	extended	extended		
Cyclone	large	large	large	large	large	large	large	large	large	large	large		
Air cyclone (l/min)	400	200	400	200	400	200	400	200	400	300	300		
Bifluorinated hexane (l/min)	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4		
Pump rate speed (rpm)	60	120	120	60	120	100	60	120	90	90	90		
Temp. Chamber out (°C)	34.9	44.5	22.1	35.5	24.4	32.7	41.3	32.2	44.6	44.9	44.2		
Time before cyclone (°C)	30.3	33.9	33.7	43.5	27.4	47.9	34	45.3	35.2	35	37.3		
Pressure drop cyclone (bar)	28.3	39.6	28.4	28.4	27	23.5	26	29.2	27.4	24.4	26.5		
Total solid dosed (g)	8.65	8.69	8.65	9.86	8.96	9.01	8.72	8.71	8.79	8.67	8.76		
Recovered solid (g)	8.57	9.42	6.99	10.28	5.18	9.84	9.31	9.99	9.67	9.56	9.74		
LOD (%)	11.34	9.4	15.56	5.42	14.48	7.47	7.74	7.94	9.23	9.3	9.52		
Reconstitution time (h:min:s)	04:51:0	05:40:0	05:47:0	04:58:0	05:13:0	05:49:0	06:26:0	06:25:0	05:17:0	05:53:0	05:35:0		
Recovery (based on weighing) and corrected LOD (%)	88.72	98.17	68.24	109.7	49.97	101.03	98.47	105.63	99.87	98.3	100.63		
Recovery based on protein analysis	54.93	81	43.18	69.47	31.69	63.07	64.37	65.71	63.71	61.34	62.93		
Actual total protein analysis (g/L)	44.7	47.6	72.2	54.1	27.2	54.4	47.8	51	48.6	46	48.8		
Recovery based on protein analysis	71.86	74.53	91.77	60.6	45.73	91.64	75.86	81.59	78.14	78.29	79.46		
actual weighed powder for reconstitution (g)	3.7519	3.7524	3.752	3.751	3.756	3.7518	3.7512	3.7509	3.751	3.751	3.7504		
Vial for reconst. 3.75g (mL)*	61.26	55.732	75.107	51.07	101.351	53.354	56.391	52.553	54.292	54.916	53.901		
Not dry (condensation wall drying chamber) Not dry (condensation wall drying chamber)													
*Volume for reconstitution: 3.75 g													
= Vial/recovered solid*3.75													
=40mL/4 g*3.75g													

FIGURE 4

assay	sample ID	sample ID	sample ID	sample ID	sample ID	sample ID	sample ID	sample ID
	N1	N2	N3	N4	N5	N6	N7	N8
TP Protein (Buret)	44.7	47.6	32.3	54.1	27.2	51.4	47.8	51.0
Electrophoresis (PAE/GE)								
Prealbumin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Alpha 1 Globulin	1.9	1.9	2.0	2.0	2.0	2.3	2.2	2.1
Alpha 2 Globulin	8.2	8.2	8.3	8.1	8.4	8.1	8.3	8.1
Beta Globulin	12.7	12.8	12.9	12.3	13.0	12.7	12.8	12.5
Gamma Globulin	9.0	9.0	9.7	9.4	9.5	9.2	9.4	9.7
Albumin	68.2	68.1	67.1	68.2	67.1	67.7	67.3	67.6
MSD								
IgG (neph)	6.70	6.55	5.13	8.41	3.85	7.44	6.70	7.56
Albumin	26.8	28.7	19.9	34.5	17.8	30.6	29.7	31.5
IgG subclasses (neph)	4.58	5.24	3.53	5.89	2.95	5.40	5.12	5.26
	1.94	2.04	1.45	2.37	1.25	2.10	1.97	2.22
	0.189	0.208	0.144	0.243	0.122	0.222	0.197	0.226
Thrombin-antithrombin complex (TAT)	0.338	0.343	0.246	0.417	0.196	0.384	0.359	0.379
	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5
Fibrinogen A (FPA)	38.9	42.1	46.4	58.9	19.5	33.0	56.8	61.7
Measles Ab								
FXIII (activity)								
Alpha 1 antitrypsin (activity)								
C1 esterase inhibitor (activity)								

FIGURE 5A

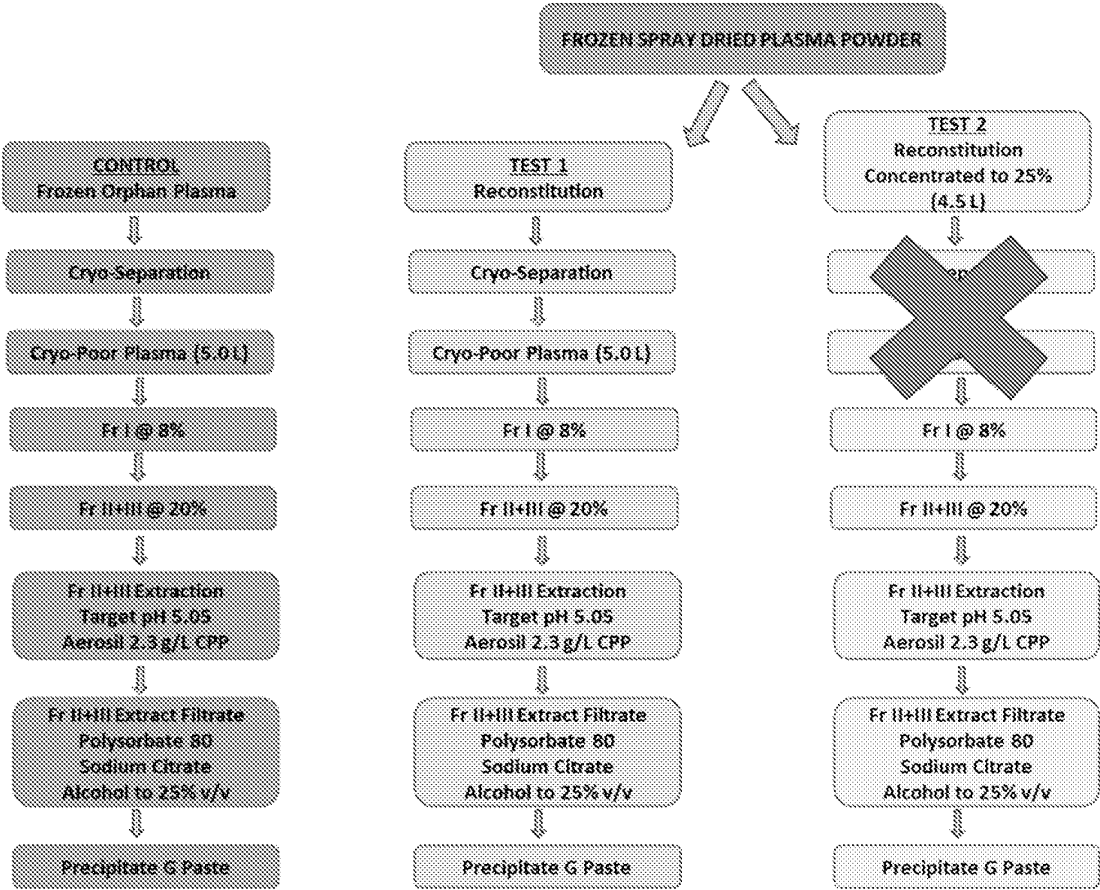


FIGURE 6

Parameter	Unit	CONTROL (Frozen Plasma)	TEST 1 (Spray Dried Plasma)	TEST 2 (Concentrated Spray Dried Plasma, Cryo precipitation and separation in one step)	TEST 3 (Cryo precipitation and separation in one step)	Reference Based on Frozen Plasma Study	Prior Range
IgG in CPP (or CRP for TEST 2)	g/L	9.3	8.84	10.95	7.72	7.3	
Albumin in CPP (or CRP for TEST 2)	g/L	39	39.3	49.45	37.00	34.9	
Albumin Recovery in Fr II+III Filtrate with sampling adjusted	% from CPP (CRP for TEST 2 and TEST 3)	91.1	88.1	89.8	78.8		
IgG recovery at Fr II+III Extract filtrate with sampling adjusted	% from CPP (CRP for TEST 2 and TEST 3)	77.6	74.9	76.1		N/A	N/A

FIGURE 7A

C3 impurity at Ppt G paste	mg/dL@5%TP	50.7	57.5	49.1		24.1	≤ 233
Fibrinogen impurity at Ppt G paste	μg/mL@5%TP (LA data)	23	22.9	23.8		5.9	≤ 201
Fibrinogen impurity at Ppt G paste	μg/mL@5%TP (Vienna Data)	13	25	9		5.9	≤ 201
FXI protein impurity at Ppt G paste	E/mL @5% TP	0.016	0.049	0.111		0.038	≤ 1.33
PL-1 impurity at Ppt G paste	nmol/ mL min @5% TP	<10	<10	<10		<10	≤ 55.3
FXII impurity at Ppt G paste	mU/mL @5% TP	5.57	4.77	3.72		<29	N/A
PKA impurity at Ppt G paste	IE/mL @5% TP	<4	<4	<4		<4	≤ 74.7
Aggregates at Ppt G paste	Polymer %	9.2	10.5	9.4		8	≤ 10.5
Protein Composition at Ppt G paste (PCA)	Gamma globulins (%)	88.8	89.2	92.7		91.9	≥ 86

FIGURE 7B

TEST 3		Reference Based on Frozen Plasma average (lowest, highest)
PKA impurity at Fr V paste	IE/mL	21.2 46.8 (<20, 97)
PKA impurity at Fr V paste	IE/g TP	0.42 7.82 (3.04, 17.3)
Aggregates at Fr V paste	Polymer %	- 0.277 (0, 0.522)
Protein Composition at Fr V paste (PCA)	Gamma globulins (%)	- 99.07 (98.45, 99.6)
Albumin at Fr V paste	mg/g TP	974 1020 (944, 1079)
HPT at Fr V Paste	mg/g TP	4.62 7.02 (3.73, 10.8)
TRF at Fr V Paste	mg/g TP	0.33 0.39 (0.056, 3.17)
AAT at Fr V Paste	mg/g TP	0.17 0.1 (0.079, 0.138)

FIGURE 7C

AAG at Fr V Paste	mg/g TP	1.50	3.66 (1.17, 15.4)
CER at Fr V Paste	mg/g TP		
		0.09	0.15 (0.053, 0.421)

FIGURE 7D