

Table 1

DRAFF SPECIFICATION FOR (S)10

ITEM	TARGET	EXPECTED RANGE	SUGGESTED SPECIFICATION	58-9-001 unheated.	
				58-9-002 unheated.	
FVIII	22.5 iu/ml	20 - 25 iu/ml	20 - 25 iu/ml	22.14	18.17
T.P.	10 g/l	7.5 - 12.5 g/l	< 15 g/l	14.8	11.8
Fibrinogen ¹	2 g/l	1.5 - 2.5 g/l	< 5 g/l	2.1	3.45
Fibronectin	4.5 g/l	3.5 - 5.5 g/l	< 1.5 g/l	8.5	7.9
Sodium	198 mM	183 - 213 mM	< 220 mM	202	220
Potassium	< 3.0 mM	No data	< 3.0 mM	0.1	0.02
Chloride	180 mM	160 - 200 mM	< 200 mM	155	172
Citrate	10 mM	No data	< 25 mM	17.1	19.7
Calcium	2 mM	No data	60 - 100 ppm ³	94.4	
Sucrose	3%	2.5 - 3.5%	< 3.5%	2.45	
Aluminium	< 1000 ppb	< 100 ppb	< 1000 ppb ²	39.2	
Zinc	< 20,000 ppb	< 10,000 ppb	< 10,000 ppb ²	9.8k	
PEG	< 0.5%	0.1 - 0.2%	< 0.5%	0.2	0.12
Heparin	< 1.0 iu/ml	1 - 1.5 iu/ml	< 2 iu/ml	3.5	2.3
Osmolality	450 mOsm/kg	450 - 500 mOsm/kg	< 500 mOsm/kg	401	
pH	6.9	6.85 - 6.95	6.8 - 7.4	6.91	6.94
H ₂ O	1.0%	0.5 - 1.0%	< 1.5%	0.82	
Other ⁴	28	78	20		