3.8 Scientific Evidence: The last 30 batches of Human Antihaemophilic Factor: Factor VIII have been produced to the following limits, at the recommended dose volume.

Test	Manufacturer's Licence Reference No.	Lower Limit Found	Upper Limit Found	Acceptable Range	Achievable Range
Solubility Time		1.5 mins	5.0 mins	0-15 mins	0-15 mins
Sterility	9.62	Pass	Pass	Pass	Pass
Toxicity	9.69	Pass	Pass	Pass	Pass
Pyrogen (Rabbit)/3 Rabbits 3ml/kg	9.70	0.8°C	3.3°C	0.0 - 4.0°C	0.0 - 4.0°C
Pyrogen (Limulus)	9.701	Pass at 1/1 dilution	Pass at 1/200 dilution	Pass at 1/100 dilution	Pass at 1/1 dilution
HB_sAg	9.71	Negative	Negative	Negative	Negative
Total Protein	9.01	32.4 g/l	53.8 g/l	<60.0 g/l	<60.0 g/l
Fibrinogen	9.01	16.9 g/l	29.0 g/l	<50.0 g/l	<50.0 g/l
% Fibrinogen		44.0	73.0	<83.0	<83.0

SNB.006.5474

3.8 Scientific Evidence: Continued

Test	Manufacturer's Licence Reference No.	Lower Limit Found	Upper Limit Found	Acceptable Range	Achievable Range
Factor VIII (BTS)	9.281	9.6 U/ml	15.0 U/ml	>6.0 U/ml	>6.0 U/ml
Factor VIII (PFC)	9.281	9.4 U/ml	16.0 U/ml	>6.0 U/ml	>6.0 U/ml
Sodium	9.04	120.0 mmol/l	192.0 mmol/l	<200.0 mmol/l	<200.0 mmol/l
Potassium	9.04	1.2 mmol/l	2.2 mmol/l	<3.0 mmol/l	<3.0 mmol/l
Chloride	9.05	51.0 mmol/l	70.0 mmol/l	<200.0 mmol/l	<200.0 mmol/l
Citrate	9.10	22.2 mmol/l	48.8 mmol/l	<80.0 mmol/l	<80.0 mmol/l
pH	9.06	7.2	7.4	7.0 ± 0.5	7.0 ± 0.5
Anti - A_1	9.17	1:8	1:64	>1:64	>1:64
Anti - B	9.17	1:4	1:64	>1:64	>1:64
% Water	9.20	1.8	2.9		

SNB.006.5475