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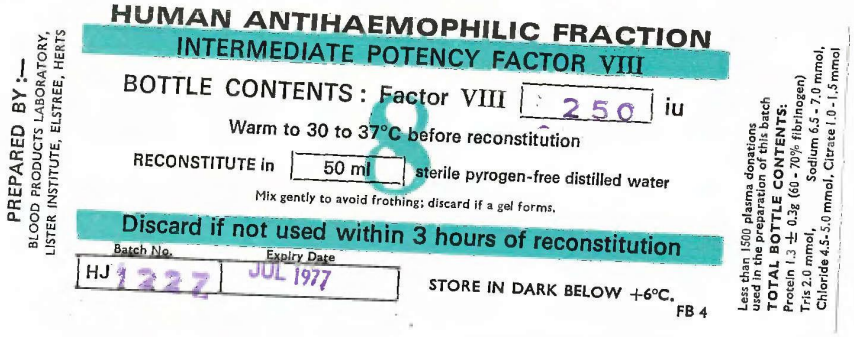
FINAL EVALUATION

Batch No. HJ 1227

Name of Product: HUMAN ANTIHAEMOPHILIC FRACTION
(Intermediate Potency Factor VIII)

Product Licence No:

Label: (Completed sample label, exactly as attached to bottles)



Formulation of Final Product: (Reconstituted in final container, as for clinical use, in 0·5 times the pre-drying volume of water)

Factor VIII:	not less than 3·0 iu/ml
Sodium ion:	not more than 200 mmol/l
Citrate ion:	not more than 55 mmol/l

Fractionation 19.8.76 (date)

Sterilisation: by membrane filtration, mean pore size 0·22µm.

Volume per bottle before freeze-drying:	100 ml (± ml)	ml (± ml)
Number of bottles filled:	196	

List of Attached Test Reports:

1. Sterility
2. Abnormal Toxicity and Pyrogenicity
3. Factor VIII Assay
4. General Tests
5. Hepatitis B antigen
6. ~~Blood Group Serology~~

I have examined the Batch Manufacturing Record and Test Reports and I pass the following number of bottles for clinical use:

179 bottles at 50 ml; 1 bottles at 50ml

GRO-C (signed) 50 y/c (position) 29.9.76 (date)

Blood Products Laboratory, Lister Institute of Preventive Medicine, Elstree, Herts.