

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)

PREPARED BY:—
 BLOOD PRODUCTS LABORATORY,
 LISTER INSTITUTE, ELSTREE, HERTS

HUMAN ANTIHAEMOPHILIC FRACTION
INTERMEDIATE POTENCY FACTOR VIII

BOTTLE CONTENTS: Factor VIII 250 iu
 Warm to 30 to 37°C before reconstitution
 RECONSTITUTE in 50 ml sterile pyrogen-free distilled water
 Mix gently to avoid frothing; discard if a gel forms.

Discard if not used within 3 hours of reconstitution

Batch No. <u>HJ 1227</u>	Expiry Date <u>JUL 1977</u>
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STORE IN DARK BELOW +6°C. FB 4

Less than 1500 plasma donations used in the preparation of this batch.
TOTAL BOTTLE CONTENTS:
 Protein 1.3 ± 0.2g (60 - 70% fibrinogen)
 Tris 2.0 mmol, Sodium 6.5 - 7.0 mmol
 Chloride 4.5-5.0 mmol, Citrate 1.0 - 1.5 mmol

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.

<u>Volume per bottle before freeze-drying:</u>	100 ml (+ ml)	ml (+ ml)
<u>Number of bottles filled:</u>	196	/

List of Attached Test Reports:

- | | |
|---------------------------------------|------------------------------------|
| 1. Sterility | 4. General Tests |
| 2. Abnormal Toxicity and Pyrogenicity | 5. Hepatitis B antiserum |
| 3. Factor VIII Assay | 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/c (position) 29.9.76 (date)

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