

FINAL EVALUATION

8CRV QC-01

File reference : QC8C0102.REP	Product : DRIED FACTOR VIII FRACTION
Date effective : 11.2.83	
Authorized by : GRO-C	Batch No.: 8 CRV 2234H

Label : (completed sample label, exactly as attached to vials)

PREPARED BY:- BLOOD PRODUCTS LABORATORY, DAGDEN LANE, ELSWICK, HANTS. Less than 7500 plasma donations were used in the preparation of this product. The reconstituted material contains, per millilitre, not more than 100g protein (5g/l), 1000 units Factor VIII (100 units/ml), 2000 units Factor IX (200 units/ml), 2000 units Factor X (200 units/ml) and 2000 units Factor XI (200 units/ml).	DRIED FACTOR VIII FRACTION (INTERMEDIATE SPECIFIC ACTIVITY) Before reconstituting, warm the bottle and water for injections to 20°C to 30°C. Add the indicated volume of water and mix gently, avoiding frothing. Discard if not used within 3 hours of reconstitution or if a gel forms. THE PREPARATION IS OF HUMAN ORIGIN AND CAN BE ASSUMED TO BE FREE OF HEPATITIS VIRUS. P.L. 0134/0007 STORE IN THE DARK BELOW +6°C. HLS	HEATED HT2 Factor VIII content (iu) 235 Dissolve in (ml) 15 Batch 8CRV 2234H Expiry DEC 85
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of expiry taken as ~~two~~ ^{one G.S.} years from date of assigning potency (20.12.84)

ulation : See BP1980 "Dried Factor VIII Fraction" and 1982 Addendum.
See also label side-panels and reports QC-14 and QC-15.

Product Licence No.: PL0134/0008

Press Summary :

Pressing batches needed

Plasma source

Number of

Fractionation

Fill (pre-)

Date of test

Number of vials

Release authority

inspection of the issue of 151 vials for clinical use
without restriction/subject to the following restrictions :

For named patients issue via BPL (N. Pettit)

Signed : GRO-C

Head of Quality Control

Date : 12.2.85

BPL/PFL.

Inventory : Inventory card completed

Initials/date:

2 reference samples removed

Initials/date: GRO-C 12.85

vials submitted to N.I.B.S.C. Initials/date: