

Batch HL 2755

Final evaluation

Name of product: HUMAN ANTIHAEMOPHILIC FRACTION
(Intermediate Purity Factor VIII Concentrate)

Product Licence No: 0134/0007.

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

PREPARED BY:-
BLOOD PRODUCTS LABORATORY
DAGGER LANE, ELSTREE, HERTS

Less than 3500 plasma donations were used in the preparation of this batch. The reconstituted material contains, per litre, not more than 75 g protein (50-75% clotable), 60 mmol Tris, 200 mmol sodium chloride and 55 mmol citrate.

DRIED HUMAN ANTIHAEMOPHILIC FRACTION
INTERMEDIATE PURITY FACTOR VIII CONCENTRATE

Before reconstituting warm the bottle and sterile pyrogen-free water to 30° to 37°C. Add the indicated volume of water and mix gently, avoiding frothing. Discard if a gel forms.

Discard if not used within 3 hours of reconstitution

STORE IN THE DARK BELOW +6°C.

Factor VIII
content (iu) 245

Dissolve in (ml)	15
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Batch HL2755

Expiry OCT 81

PL 0134/0007

Formulation of final product: See BP 1978 p.11 "Dried Antihaemophilic Fraction"

OCTOBER 20. 20-01

Final evaluation

Batch HL 2756

Name of product: HUMAN ANTIHAEMOPHILIC FRACTION
(Intermediate Purity Factor VIII Concentrate)

Product Licence No: 0134/0007.

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

PREPARED BY:
BLOOD PRODUCTS LABORATORY
1A11GIRIANE FISTREE, MERTIS

less than 5000 plaque-forming units were used in the preparation of this batch. The reconstituted material contains, per litre, not more than 75 g protein (50/75% colloidal 60 mesh Tm, 200 mesh sediment 200 mesh + ultrafine and 55 mesh + ultrafine).

DRIED HUMAN ANTIHAEMOPHILIC FRACTION

INTERMEDIATE PURITY FACTOR VIII CONCENTRATE

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
CANNOT BE ASSUMED TO BE FREE OF HEPATITIS VIRUS

STORE IN THE DARK BELOW +6°C.

Factor VIII content (i.u.) 250

Dissolve in (ml) 15

Batch **HL 2756**

Expiry **OCT 81**

P: 0134 0007

Formulation of final product: See BP 1978 p.11 "Dried Antihaemophilic Fraction"
Label side-panels
Summary of Quality Control tests, QC-02 etc.

Fractionation date: 11/9/80

Sterilisation date: 11/9/80

Factor VIII assay date (for expiry): 3.10.80

Sub-batches included in this batch:

540	2		
35 ml	35 ml	ml	ml

Vials filled at 35 ml before freeze-drying.

Contents recommended for re-solution in 15 ml water for injection