

Final evaluationBatch HL 2755

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, BACCHAMAN, ESTER, HENTZ, 200 mg/ml concentrate and 50 mg/ml dilute.	<b>DRIED HUMAN ANTIHAEMOPHILIC FRACTION</b> INTERMEDIATE PURITY FACTOR VIII CONCENTRATE		Factor VIII content (iu) 245
	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.		Dissolve in (ml) 15
	Discard if not used within 3 hours of reconstitution		Batch HL2755
	STORE IN THE DARK BELOW +6°C. HL3		Expiry 0CT81 PL0134/0007

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

OCTOBER 80 QC-02

Final evaluationBatch 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, BACCHAMAN, ESTER, HENTZ, 200 mg/ml concentrate and 50 mg/ml dilute.	<b>DRIED HUMAN ANTIHAEMOPHILIC FRACTION</b> INTERMEDIATE PURITY FACTOR VIII CONCENTRATE		Factor VIII content (iu) 250
	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.		Dissolve in (ml) 15
	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.		Batch HL2756
	STORE IN THE DARK BELOW +6°C. HL4		Expiry 0CT81 PL 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 Injections