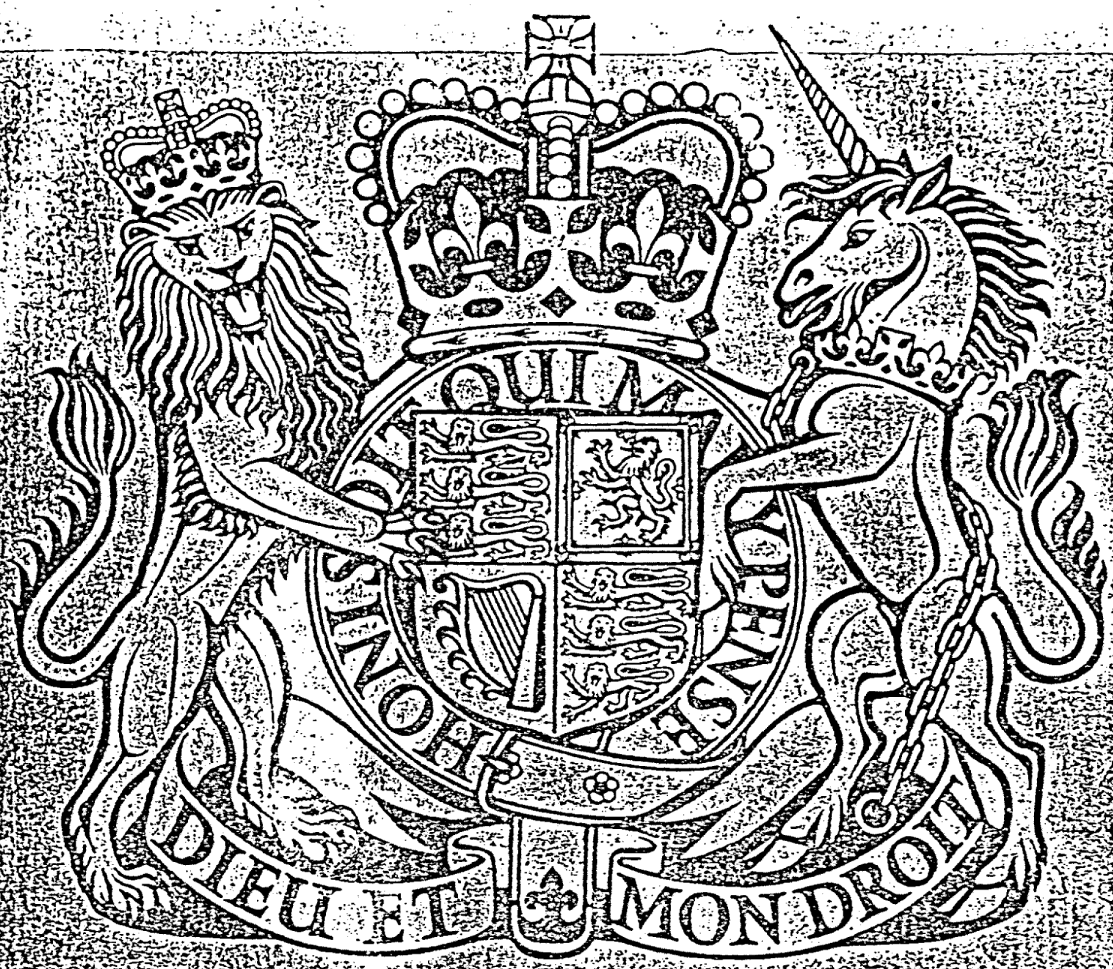

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minimum, after which the blood shall immediately be cooled again to 4° to 6°.

Labelling The label on the container states (1) the ABO group; (2) the Rh group and the nature of specific antisera used in testing; (3) the total volume of fluid, the proportion of blood, and the nature and percentage of anticoagulant and of any other material introduced; (4) a means whereby the individual source of the blood may be identified; (5) the date on which the blood was withdrawn; (6) the date after which the preparation is not suitable for transfusion; (7) the conditions under which it should be stored; (8) that the contents should not be used if there is any visible evidence of deterioration; (9) for blood of group O, that a test for hæmolysins has been carried out and, if a positive result has been obtained, that the blood is unsafe for transfusion to recipients belonging to other groups.

Whole Blood should be administered only with suitable equipment such as that described in Section 3 or Section 4 of British Standard 2463:1962, Transfusion Equipment for Medical Use.

Concentrate of Red Blood Cells

Concentrated Human Red Blood Corpuscles

Concentrate of Red Blood Cells is prepared from one or more preparations of Whole Blood which are preferably not more than fourteen days old and each of which has already been directly matched with the blood of the intended recipient.

A quantity of plasma and anticoagulant solution equivalent to not less than 40 per cent of the total volume is removed from the Whole Blood.

Description A dark red fluid when prepared; after standing the red cells may form a sediment, leaving a supernatant layer of yellow plasma.

Hæmoglobin value Not less than 15.5 per cent w/v, expressed in terms of the Cyanmethæmoglobin Solution for Photometric Hæmoglobinometry (British Standard 3985:1966).

Storage Concentrate of Red Blood Cells should be kept in a sterile container sealed so as to exclude micro-organisms and stored at a temperature of 4° to 6°.

Labelling The label on the container states (1) the reference numbers of the containers of the Whole Blood from which the preparation was made; (2) the ABO group of the Whole Blood from which the preparation was made; (3) the Rh group of the Whole Blood from which the preparation was made and the nature of the specific antisera used in testing; (4) the date after which the preparation is not suitable for transfusion; (5) the conditions under which the preparation should be stored; (6) that the preparation should not be used if there is any visible evidence of deterioration.

Concentrate of Red Blood Cells should be administered only with suitable equipment such as that described in Section 3 or Section 4 of British Standard 2463:1962, Transfusion Equipment for Medical Use.

Albumin

Human Albumin

Albumin is a solution in water of human albumin containing a low proportion of salt. It is prepared from pooled liquid plasma obtained from blood from human subjects (a) who are, as far as can be ascertained by a registered medical practitioner after simple clinical examination and consideration of their medical history, free from disease transmissible by blood transfusion, (b) whose blood has been tested with negative results for evidence of syphilitic infection, (c) whose blood has been tested with negative results for the presence of hepatitis B antigen by a method not less sensitive than reversed passive hæmagglutination, and (d) the hæmoglobin value of whose blood in terms of the Cyanmethæmoglobin Solution for Hæmoglobinometry (British Standard 3985:1966) is not less than 12.5 per cent w/v (female donors) or not less than 13.3 per cent w/v (male donors).

The albumin fraction, prepared by a suitable fractionation technique, is dissolved in water and, at pH 7.0, sodium caprylate or other suitable substances are added to stabilise it to heat. No bactericide or antibiotic is added at any stage during preparation. The solution is sterilised by *Filtration* and distributed aseptically into sterile containers, which are then sealed so as to exclude micro-organisms. The solution is then heated to, and maintained for ten hours at, 59.5° to 60.5° so as to prevent the transmission of serum hepatitis. Finally, the containers are incubated for not less than fourteen days at 30° to 32° and examined visually for signs of microbial contamination.

Albumin contains not less than 15 and not more than 25 per cent w/v of protein, and not more than 0.65 millimole of sodium ions, 0.05 millimole of potassium ions, and 0.1 millimole of citrate ions per g of protein.

Description A clear liquid. The colour ranges from amber to deep orange-brown with increasing protein concentration.

Identification A. By electrophoresis, using the moving boundary technique, in a buffer of barbitone and its sodium salt at pH 8.6 and ionic strength 0.1, not less than 96 per cent of the protein present has the mobility of human albumin (the component representing over 50 per cent of the proteins of normal human plasma).

Acidity or alkalinity pH, 6.7 to 7.3, Appendix V L.

Hæm Dilute with sufficient *saline solution* to produce a solution containing 1.0 per cent w/v of protein; the *absorbance* of the resulting solution at 403 nm, Appendix II B, is not more than 0.25.

Denatured protein Equilibrate a column, 60 to 75 cm long and 2.5 to 3.0 cm in diameter, of a gel of a cross-linked dextran suitable for fractionation of proteins in the range of molecular weights from 5000 to 150,000 with a lower

Identification; Acidity or alkalinity; Denatured protein When dissolved in a volume of *water* to give a protein concentration of 5 per cent w/v, the solution complies with the requirements stated under Albumin.

Loss on drying When dried over *phosphorus pentoxide* at a pressure not exceeding 2.7 Pa (about 0.02 torr) for twenty-four hours, loses not more than 0.5 per cent of its weight.

Sterility Complies with the *test for sterility*, Appendix XVI A.

Pyrogens When dissolved in a volume of *sodium chloride injection* to give a protein concentration of 5 per cent w/v, complies with the *test for pyrogens*, Appendix XIV K, using 10 ml per kg of the rabbit's weight.

Abnormal toxicity When dissolved in a volume of *water for injections* to give a protein concentration of 25 per cent w/v, complies with the *test for abnormal toxicity*, Appendix XIV L, using Method B.

Assay Dissolve in a volume of *water* equal to the volume of Water for Injections stated on the label and carry out the Assay described under Albumin.

Storage Dried Albumin should be kept in an atmosphere of nitrogen, in a sterile container sealed so as to exclude micro-organisms and as far as possible moisture, protected from light, and stored at a temperature between 2° and 25°.

Labelling The label on the container states (1) the volume of Water for Injections necessary to reconstitute the solution to 25 per cent w/v protein concentration; (2) the concentration of sodium, potassium and citrate ions; (3) the names and concentrations of stabilising agents and any other added substances present; (4) that the container must not be shaken to hasten solution of the solids; (5) that the contents must not be used if, after adding water, a gel forms or solution is incomplete; (6) that the solution must be discarded if not used within three hours; (7) the date after which the contents are not intended to be used; (8) the conditions under which it should be stored.

Dried Albumin, after reconstitution, should be administered only with suitable equipment such as that described in Section 3 or Section 4 of British Standard 2463:1962, Transfusion Equipment for Medical Use.

Dried Factor VIII Fraction

Dried Human Antihæmophilic Fraction

Dried Factor VIII Fraction is prepared from human plasma; it is rich in clotting factor VIII. Plasma to be used for preparing Dried Factor VIII Fraction is obtained from blood from human subjects to whom all of the conditions (a) to (d) described under Albumin apply. The antihæmophilic fraction is prepared by a suitable fractionation technique from plasma separated from cellular components by a suitable method. The fraction so obtained is dissolved in an appropriate liquid and the resulting solution is sterilised by *Filtration*, distributed in sterile containers, and dried from the frozen state. The air is removed or replaced by *oxygen-free nitrogen* and the containers are sealed so as to exclude micro-organisms. No preservative is added.

When the contents of a sealed container are dissolved in a volume of *water* equal to the volume of Water for Injections stated on the label, the resulting solution contains not less than 3.0 Units per ml and not less than 0.1 Unit per mg of protein of which not more than 80 per cent is fibrinogen, not more than 200 millimoles of sodium ions per litre and not more than 55 millimoles of citrate ions per litre.

Description A white powder or friable solid.

For the following tests, where it is directed that a solution is to be used, dissolve the contents of the sealed container in a volume of the appropriate solvent equivalent to the volume of Water for Injections stated on the label.

Solubility in water Slowly add *water*, at a temperature between 18° and 22°, to the substance being examined, at the same temperature. Mix gently by rotation, avoiding frothing. The substance dissolves completely within twenty minutes forming a clear or slightly opalescent solution.

Identification A freshly prepared solution in *water* has the property of correcting the clotting abnormality in plasma deficient in clotting factor VIII, when tested by a method specific for clotting factor VIII.

Acidity or alkalinity Dissolve in *carbon dioxide-free water*; pH of the resulting solution, 6.8 to 7.4, Appendix V L.

Loss on drying When dried over *phosphorus pentoxide* at a pressure not exceeding 2.7 Pa (about 0.02 torr) for twenty-four hours, loses not more than 0.5 per cent of its weight.

Pyrogens When dissolved in *water for injections*, complies with the *test for pyrogens*, Appendix XIV K, using a volume equivalent to not less than 10 Units per kg of the rabbit's weight.

Sterility Complies with the *test for sterility*, Appendix XVI A.

Abnormal toxicity When dissolved in *water for injections*, complies with the *test for abnormal toxicity*, Appendix XIV L, using Method B and using a volume of the solution equivalent to not less than 75 Units per kg of body weight.

Assay Dissolve in *water*.

For total protein. Carry out the method for *determination of protein in blood products*, Appendix VIII H, Method VI.

For fibrinogen. Dilute 1 ml of the solution to 10 ml with a phosphate-saline buffer at pH 6.5 and ionic strength 0.15. Clot 5 ml of the dilution with the minimal amount of thrombin, collect the clot, transfer it to a 75-ml boiling-tube and carry out the method for *determination of protein in blood products*, Appendix VIII H, Method VI, beginning at the words 'add 2 ml of a solution containing 75 per cent...' and ending at the words '...as indicator'. Each ml of 0.02M *hydrochloric acid VS* is equivalent to 1.75 mg of fibrinogen.

For sodium ions. To 10 ml of the solution add sufficient *water* to produce 100 ml, dilute 10 ml to 500 ml with *water* and determine by Method II for *atomic emission spectrophotometry*, Appendix II D, measuring at 589 nm and using *sodium solution ASp* suitably diluted with *water* as the standard solution.

For citrate ions. Carry out the Assay *for citrate ions* described under Albumin, using 1 ml of the solution.

For potency. Carry out the *biological assay of factor VIII fraction*, Appendix XIV D1. The estimated potency is not