Assay Dissolve in *water*. To 2 ml of the resulting solution in a round-bottomed centrifuge tube add 2 ml of a 7.5 per cent w/v solution of *sodium molybdate* and 2 ml of a mixture of 1 volume of *nitrogen-free sulphuric acid* and 30 volumes of *water*. Shake, centrifuge, decant the supernatant liquid, and allow the inverted tube to drain on filter paper. Using the residue thus obtained, carry out Method III for the *determination of nitrogen*, Appendix VIII H, and multiply the result by 6.25 to obtain the protein content.

Storage Dried Plasma should be kept in an atmosphere of nitrogen or *in vacuo* 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 below 25°.

Labelling The label on the container states (1) the name and percentage of anticoagulant and of any other material introduced; (2) that the contents are derived from not more than 12 donations of blood; (3) the quantity of Water for Injections necessary to reconstitute the solution; (4) the protein content of the reconstituted solution; (5) that the reconstituted solution should be used as soon as possible and in any case within three hours of reconstitution; (6) the date after which the preparation is not intended to be used for transfusion; (7) the conditions under which it should be stored.

Dried Plasma, after reconstitution, should be administered only with suitable equipment such as that described in Section 3 or Section 4 of British Standard 2436:1962, Transfusion Equipment for Medical Use.

Plasma Protein Fraction

Human Albumin Fraction (Saline)

Plasma Protein Fraction is a solution of the proteins of liquid human plasma, containing albumin and globulins that retain their solubility on heating. It exerts a colloid osmotic pressure approximately equivalent to that of pooled liquid human plasma containing 5.2 per cent w/v of protein; it contains no fibrinogen or antibodies. It is prepared from pooled liquid plasma obtained from blood from human subjects to whom all the conditions (a) to (d) described under Albumin apply. The albumin fraction, prepared by a suitable fractionation technique, is dissolved in water and sufficient sodium caprylate or other suitable substances are added to stabilise it to heat, and Sodium Chloride is added to adjust the content of sodium ions to between 130 and 160 millimoles per litre. No bactericide or antibiotic is added at any stage during preparation. The solution is sterilised by *Filtration*, distributed aseptically in sterile containers, and sealed so as to exclude micro-organisms. It is then heated to, and maintained for ten hours at, 59.5° to 60.5° so as to prevent the transmission of hepatitis. Finally, the containers are incubated for not less than fourteen days at 30° to 32° and examined visually for signs of microbial contamination.

Plasma Protein Fraction contains not less than 4.3 per cent w/v of total protein, not more than 15 millimoles of citrate ions per litre, and not more than 2 millimoles of potassium ions per litre.

Description An amber liquid which may produce a slight deposit on storage.

Identification 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 90 per cent of the protein present has the mobility of albumin, the remainder being globulins in which gamma globulin is not detectable.

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 Complies with the test described under Albumin, except that the weight of protein in the fraction of the eluate is not more than 5 per cent of the weight of protein in the volume of the substance being examined applied to the column.

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

Pyrogens Complies with the *test for pyrogens*, Appendix XIV K, using 10 ml per kg of the rabbit's weight.

Abnormal toxicity Complies with the *test for abnormal toxicity*, Appendix XIV L, using Method B.

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

For citrate ions. Carry out the Assay *for citrate ions* described under Albumin, using 2 ml.

For potassium ions. Dilute 10 ml to 200 ml with *water* and determine by Method II for *atomic emission spectrophotometry*, Appendix II D, measuring at 767 nm and using *potassium solution ASp* suitably diluted with *water* as the standard solution.

For sodium ions To 10 ml 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.

Storage Plasma Protein Fraction should be stored at a temperature between 2° and 25°, protected from light.

Labelling The label on the container states (1) the volume of the preparation; (2) the total amount of protein; (3) the concentrations of sodium, potassium, and citrate ions; (4) the names and concentrations of stabilising agents and any other added substances present in the final solution; (5) that the contents must not be used if the solution is turbid or contains more than a trace of fine deposit; (6) the date after which the preparation is not intended to be used; (7) the conditions under which it should be stored.