"PART XII B
REQUIREMENTS FOR THE FUNCTIONING AND OPERATION OF A BLOOD BANK AND / OR FOR PREPARATION OF BLOOD COMPONENTS.

I. BLOOD BANKS / BLOOD COMPONENTS

A. GENERAL

1. Location and Surroundings : The blood bank shall be located at a place which shall be away from open sewage, drain, public lavatory or similar unhygienic surroundings.

2 Building : The building (s), used for operation of a blood bank and/or preparation of blood components shall be constructed in such a manner so as to permit the operation of the blood bank and preparation of blood components under hygienic conditions and shall avoid the entry of insects, rodents and flies. It shall be well lighted, ventilated and screened (mesh), wherever necessary. The walls and floors of the rooms, where collection of blood or preparation of blood components or blood products is carried out shall be smooth, washable and capable of being kept clean. Drains shall be of adequate size and where connected directly to a sewer, shall be equipped with traps to prevent back siphonage.

3. Health, clothing and sanitation of staff : The employees shall be free from contagious or infectious diseases. They shall be provided with clean overalls, head-gears, foot-wears and gloves, wherever required. There shall be adequate, clean and convenient hand washing and toilet facilities.

B. ACCOMODATION FOR A BLOOD BANK :

A blood bank shall have an area of 100 square meters for its operations and an additional area of 50 square meters for preparation of blood components. It shall be consisting of a room each for –

(1) Registration and medical examination with adequate furniture and facilities for registration and selection of donors;

(2) blood collection (air-conditioned);

(3) blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degree centigrade to 25 degree centigrade);

(4) laboratory for blood group serology. (air-conditioned)

(5) laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV-antibodies (air-conditioned);

(6) sterilization-cum-washing;

(7) refreshment-cum-rest room (air-conditioned);

(8) store-cum-records.

NOTES :

(1) The above requirements as to accommodation and area may be relaxed, In respect of testing laboratories and sterilization-cum-washing room, for reasons to be recorded in writing by the Licensing Authority and / or the Central Licence Approving Authority, in respect of blood banks operating in Hospitals, provided the hospital concerned has a pathological laboratory and a sterilization-cum-washing room common with other departments in the said hospital.

(2) Refreshments to the donor after phlebotomy shall be served so that he is kept under observation in the Blood Bank.

C. PERSONNEL

Every blood bank shall have following categories of whole time competent technical staff :-

(a) Medical Officer, possessing the qualifications specified in condition of rule 122-G.

(b) Blood Bank Technician(s) ,possessing -

(i) Degree in Medical Laboratory Technology (M.L.T.) with six months' experience in the testing of blood and/or its components; or

(ii) Diploma in Medical Laboratory Technology (MLT) with one year's experience in the testing of blood and/or its components, the degree or diploma being from a University/Institution recognised by the Central Government or State Government.

(c) Registered Nurse(s).

(d) Technical Supervisor(where blood components are manufactured), possessing -

(i) Degree in Medical Laboratory Technology (M.L.T.) with six months' experience in the preparation of blood components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year's experience in the preparation of blood components, the degree or diploma being from a University/Institution recognised by the Central Government or State Government.

NOTES:

(1) The requirements of qualification and experience in respect of Technical Supervisor and Blood Bank Technician shall apply in the cases of persons who are approved by the Licensing Authority and/or Central Licence Approving Authority after the commencement of the Drugs and Cosmetics(Amendment) Rules, 1999.

(2) As regards, the number of whole time competent technical personnel, the blood bank shall comply with the requirements laid down in the Directorate General of Health Services Manual.

(3) It shall be the responsibility of the licensee to ensure through maintenance of records and other latest techniques used in blood banking system that the personnel involved in blood banking activities for collection, storage, testing and distribution are adequately trained in the current Good Manufacturing Practices/Standard Operating Procedures for the tasks undertaken by each personnel. The personnel shall be made aware of the principles of Good Manufacturing Practices/Standard operating Procedures that affect them and receive initial and continuing training relevant to their needs.

D. MAINTENANCE ;

The premises shall be maintained in a clean and proper manner to ensure adequate cleaning and maintenance of proper operations. The facilities shall include –

(1) Privacy and thorough examination of individuals to determine their suitability as donors.

(2) Collection of blood from donors with minimal risk of contamination or exposure to activities and equipment unrelated to blood collection.

(3) Storage of blood or blood components pending completion of tests.

(4) Provision for quarantine, storage of blood and blood components in a designated location, pending repetition of those tests that initially give questionable serological results.

(5) Provision for quarantine, storage, handling and disposal of products and reagents not suitable for use.

(6) Storage of finished products prior to distribution or issue.

(7) Proper collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.

(8) Adequate and proper performance of all procedures relating to plasmapheresis, plateletpheresis and leucapheresis.

(9) Proper conduct of all packaging, labeling and other finishing operations.

(10) Provision for safe and sanitary disposal of –

(i) Blood and/or blood components not suitable for use, distribution or sale.

(ii) Trash and items used during the collection, processing and compatibility testing of blood and/or blood components.

E. EQUIPMENT :

Equipment used in the collection, processing, testing, storage and sale/distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance. The equipment shall be observed, standardised and calibrated on a regularly scheduled basis as described in the Standard Operating Procedures Manual and shell operate in the manner for which it was designed so as to ensure compliance with the official requirements (the equipments) as stated below for blood and its components.

Equipment that shall be observed, standardised and calibrated with at least the following frequencies :-

	EQUIPMENT	PERFORMANCE	FREQUENCY	FREQUENCY OF CALIBRATION
1.	Temperature recorder	Compare against thermometer	Daily	As often as necessary
2.	Refrigerated centrifuge	Observe speed and temperature	Each day of use	As often as necessary
3.	Hematocrit centrifuge	--	--	Standardise before initial use, after repair or adjustments, and annually.
4.	General lab. centrifuge	--	--	Tachometer. every 6 months,
5.	Automated Blood typing	Observe controls for correct results	Each day of use	---
6.	Haemoglo-bihometer	Standardize against cyanamethemo-globulin standard	Each day of use	---
7.	Refractiometer or Urinometer	Standardize against distilled water .	---ditto ---	---
8.	Blood container weighing device	standardize against container of known weight	---ditto --	As often as necessary,
9.	Water Bath	Observe Temperature	---ditto --	----ditto----
10.	Rh view box(wherever necessary)	--ditto --	--ditto--	----ditto----
11.	Autoclave	--ditto --	Each time	-- ditto --

			of use	
12.	serologic rotators	Observe controls for correct results	Each day of use	speed as often as necessary
13.	Laboratory thermometers	--	--	Before initial use
14.	Electronic thermometers	--	Monthly	--
15.	Blood agitator	Observe weight of the first container of blood filled for correct results	Each day of use	standardize with container of known mass or volume before initial use, and after repairs or adjustments.

F. SUPPLIES AND REAGENTS:

All supplies and reagents used in the collection, processing, compatibility, testing, storage and distribution of blood and blood components shall be stored at proper temperature in a safe and hygienic place, in a proper manner and in particular –

(a) all supplies coming and contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product.

(b) supplies and reagents that do not bear an expiry date shall be stored in a manner that the oldest is used first.

(c) supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer .

(d) all final containers and closures for blood and blood components not intended for transfusion shall be clean and free of surface solids and other contaminants.

(e) each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling. Such examination shall include inspection for breakage of seals, when indicated, and abnormal discoloration. Where any defect is observed, the container shall not be used or, if detected after filling, shall be properly discarded.

(f) representative samples of each lot of the following reagents and/or solution shall be tested regularly on a scheduled basis by methods described in the Standard Operating Procedures Manual to determine their capacity to perform as required :

Reagents and solutions	Frequency of testing alongwith controls

Anti-human serum	Each day of use
Blood grouping serums	Each day of use
Lectin	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Hepatitis test reagents	Each run
Syphilis serology reagents	Each run
Enzymes	Each day of use
HIV I and II reagents	Each run
Normal saline (LISS and PBS)	Each day of use
Bovine Albumin	Each day of use

G. GOOD MANUFACTURING PRACTICES (GMPs) / STANDARD OPERATING PROCEDURES (SOPs):

Written Standard Operating Procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage and sale or distribution of blood and/or preparation of blood components for homologous transfusion, autologous transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the concerned areas. The Standard Operating Procedures shall inter alia include :

1. (a) criteria used to determine donor suitability.

(b) methods of performing donor qualifying tests and measurements Including minimum and maximum values for a test or procedure, when a factor in determining acceptability;

(c) solutions and methods used to prepare the site of phlebotomy so as to give maximum assurance of a sterile container of blood;

(d) method of accurately relating the product(s) to the donor;

(e) blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood drawn from the donor;

(f) methods of component preparation including, any time restrictions for specific steps in processing;

(g) all tests and repeat tests performed on blood and blood components during processing;

(h) pre-transfusion testing, wherever applicable, including precautions to be taken to identify accurately the recipient blood components during processing;

(i) procedures of managing adverse reactions in donor and recipient reactions

(j) storage temperatures and methods of controlling storage temperatures for blood and its components and reagents;

(i) length of expiry dates, if any, assigned for all final products;

(I) criteria for determining whether returned blood is suitable for re-issue;

(m) procedures used for relating a unit of blood or blood component from the donor to its final disposal;

(n) quality control procedures for supplies and reagents employed in blood collection, processing and re-transfusion testing;

(o) schedules and procedures for equipment maintenance and calibration;

(p) labelling procedures to safe guard its mix-ups, receipt, issue, rejected and in-hand;

(q) procedures of plasmapheresis, plateletphersis and leucapheresis if performed, including precautions to be taken to ensure re-infusion of donor's own cells.

(r) procedures for preparing recovered (salvaged) plasma if performed, including details of separation, pooling, labeling, storage and distribution.

(s) all records pertinent to the lot or unit maintained pursuant to these regulations shall be reviewed before the release or distribution of a lot or unit of final product. The review or portions of the review may be performed at appropriate periods during or after blood collection, processing, testing and storage A thorough investigation, including the conclusions and follow-up, of any unexplained discrepancy or the failure of a lot or unit to meet any of its specification shall be made and recorded;

2. A licensee may utilise current Standard Operating Procedures, such as the Manuals of the following organisations, so long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this Part, namely :-

(i) Directorate General of Health Services Manual.
(ii) Other Organisations or individual blood bank's manuals, subject to the approval of State Licensing Authority and Central Licence Approving Authority.

H. CRITERIA FOR BLOOD DONATION :

Conditions for donation of blood :

(1) General -No person shall donate blood and no blood bank shall draw blood from a person, more than once in three months. The donor shall be in good health, mentally alert and physically fit and shall not be inmates of jail, persons having multiple sex partners and drug-addicts. The donors shall fulfill the following requirements, namely :-

(a) the donor shall be in the age group of 18 to 60 years.
(b) the donor shall not be less than 45 kilograms;
(c) temperature and Pulse of the donor shall be normal;
(d) the systolic and diastolic blood pressures are within normal limits without medication;
(e) haemoglobin which shall not be less than 12.5 grams;
(f) the donor shall be free from acute respiratory diseases;
(g) the donor shall be free from any skin diseases at the site of phlebotomy ;
(h) the donor shall be free from any disease transmissible by blood transfusion, insofar as can be determined by history and examination indicated above;
(i) the arms and forearms of the donor shall be free from skin punctures or scars indicative of professional blood donors or addiction of self injected narcotics

(2) Additional qualifications of a donor. -No person shall donate blood, and no blood bank shall draw blood from a donor, in the conditions mentioned in column (1) of the Table given below before the expiry of the period of deferment mentioned in the column (2) of the said Table.

Table: Deferment of blood donation

CONDITIONS (1)	**PERIOD OF DEFERMENT** (2)
(a) Abortions	6 months
(b) History of Blood transfusion	6 months
(c) Surgery	12 months
(d) Typhoid	12 months after recovery
(e) History of Malaria and	3 months (endemic)
duly treated	3 years (non endemic area)
(f) Tattoo	6 months
(h) Breast feeding	12 months after delivery
(i) Immunization (Cholera, Typhoid, Diphtheria, Tetanus, Plague, Gammaglobulin)	15 days
(j) Rabies vaccination	1 year after vaccination

(k) History of Hepatitis in family or close contact	12 months
(l) Immunoglobulin	12 months.

(3) No person shall donate blood and no brood bank shall draw blood from a person, suffering from any of the diseases mentioned below, namely .-

a. Cancer
b. Heart disease
c. Abnormal bleeding tendencies
d. Unexplained weight loss
e. Diabetes-controlled on Insulin
f. Hepatitis infection
g. Chronic nephritis
h. Signs and symptoms, suggestive of AIDS
i. Liver disease
j. Tuberculosis
k. Polycythemia Vera
l. Asthma
m. Epilepsy
n. Leprosy
o. Schizophrenia
p. Endocrine disorders

I. GENERAL EQUIPMENTS AND INSTRUMENTS :

1. For blood collection room :

(i) Donor beds, chairs and tables: These shall be suitably and comfortably cushioned and shall be of appropriate size.
(ii) Bedside table.
(iii) Sphygmomanometer and Stethoscope.
(iv) Recovery beds for donors.
(v) Refrigerators, for storing separately tested and untested blood, maintaining temperature between 2 to 6 degree centigrade with digital dial thermometer, recording thermograph and alarm device, with provision for continuous power supply.
(vi) Weighing devices for donor and blood containers.

2. For haemoglobin determination :

(i) Copper sulphate solution (specific gravity 1.053)
(ii) Sterile lancet and impregnated alcohol swabs.
(ii) Capillary tube (1.3x1.4x96 mm or pasteur pipettes)
(iv) Rubber bulbs for capillary tubings.
(v) Sahli's haemoglobinometer/Colorimeteric method.

3. For temperature and pulse determination:
(i) Clinical thermometers.
(ii) Watch (fitted with a seconds-hand) and a stop-watch.

4. For blood containers :

(a) Only disposable PVC blood bags shall be used (closed system) as per the specifications of IP/USP/BP.
(b) Anti-coagulants: The anti-coagulant solution shall be sterile, pyrogen-free and of the following composition that will ensure satisfactory safety and efficacy of the whole blood and/or for all the separated blood components.
(i) Citrate Phosphate Dextrose Adenine solution (CPDA) or Citrate Phosphate Dextrose Adenine- 1 (CPDA-1) ----14 ml. Solution shall be required for 100 ml of blood.

NOTE 1. (i) In case of single/double/triple/quadruple blood collection bags used for blood component preparations, CPDA blood collection bags may be used.
(ii) Acid Citrate Dextrose solution (A.C.D with Formula-A). I.P. -- 15ml. Solution shall be required for 100ml of blood.
(iii) Additive solutions such as SAGM, ADSOL, NUTRICEL may be used for storing, and retaining Red Blood Corpuscles upto 42 days.

NOTE2. The licensee shall ensure that the anti-coagulant solutions are of a licensed manufacturer and the blood bags in which the said solutions are contained have a certificate of analysis of the said manufacturer.

5. Emergency equipments/items .

(i) Oxygen cylinder with mask, gauge and pressure regulator.
(ii) 5 percent Glucose or Normal Saline.
(iii) Disposable sterile syringes and needles of various sizes.
(iv) Disposable sterile I.V. infusion sets.
(v) Ampoules of Adrenaline, Noradrenaline, Mephentin, Betamethasone or Dexamethasone, Metoclorpropamide injections
(vi) Aspirin.

6. Accessories :

(i) Such as blankets, emesis basins, haemostats, set clamps, sponge forceps, gauze, dressing jars, solution jars, waste cans.
(ii) Medium cotton balls, 1.25 cm. adhesive tapes.
(iii) Denatured spirit, Tincture Iodine, green soap or liquid soap.

(iv) Paper napkins or towels.
(v) Autoclave with temperature and pressure indicator.
(vi) Incinerator
(vii) Stand-by generator.

7. Laboratory equipment:

(i) Refrigerators, for storing diagnostic kits and reagents, maintaining a temperature between 4 to 6 degree ceritigrade (plus/minus 2 degree centigrade) with digital dial thermometer having provision for continuous power supply.
(ii) Compound Microscope with low and high power objectives.
(iii) Centrifuge Table Model
(iv) Water bath: having range between 37 degree centigrade to 56 degree centigrade
(v) Rh viewing box in case of slide technique.
(vi) Incubator with thermostatic control.
(vii) Mechanical shakers for serological tests for Syphilis.
(viii) Hand-lens for observing tests conducted in tubes.
(ix) Serological graduated pipettes of various sizes
(x) Pipettes (Pasteur)
(xi) Glass slides
(xii) Test tubes of various sizes/micrometer plates (U or V type)
(xiii) Precipitating tubes 6mmx50mm of different sizes and glass beakers of different sizes
(xiv) Test tube racks of different specifications.
(xv) Interval timer electric or spring wound. .
(xvi) Equipment and materials for cleaning glass wares adequately.
(xvii) Insulated containers for transporting blood, between 2 degree centigrade to 10 degree centigrade temperatures, to wards and hospitals.
(xviii) Wash bottles
(xix) Filter papers
(xx) Dielectric tube sealer.
(xxi) Plain and EDT A vials
(xxii) Chemical balance (wherever necessary)
(xxiii) ELISA reader with printer, washer and micropipettes.

J. SPECIAL REAGENTS:

(1) Standard blood grouping sera Anti A, Anti B and Anti D with known controls. Rh typing sera shall be in double quantity and each of different brand or if from the same, supplier each supply shall be of different lot numbers.
(2) Reagents for serological tests for syphilis and positive sera for controls.
(3) Anti Human Globulin Serum (Coomb's serum)
(4) Bovine Albumin 22 percent Enzyme reagents for incomplete antibodies.
(5) ELISA or RPHA test kits for Hepatitis and HIV I & II.

(6) Detergent and other agents for cleaning laboratory glasswares.

K. TESTING OF WHOLE BLOOD :

(1) It shall be responsibility of the licensee to ensure that the whole blood collected, processed and supplied conforms to the standards laid down in the Indian Pharmacopoeia and other tests published, if any, by the Government.

(2) Freedom from HIV antibodies (AIDS) Tests -Every licensee shall get samples of every blood unit tested, before use, for freedom from HIV I and HIV II antibodies either from laboratories specified for the purpose by the Central Government or in his own laboratory. The results of such testing shall be recorded on the label of the container.

(3) Each blood unit shall also be tested for freedom from Hepatitis B surface antigen, and Hepatitis C Virus antibody VDRL and malarial parasite and results of such testing shall be recorded on the label of the container.

NOTE:

(a) Blood samples of donors in pilot tube and the blood samples of the recipient shall be preserved for 7 days after issue.
(b) The blood intended for transfusion shall not be frozen at any stage.
(c) Blood containers shall not come directly in contact with ice at any stage.

L. RECORDS :

The records which the licensee is required to maintain shall include inter alia the following particulars, namely:-

(1) Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer In-charge.

(2) Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L., Hepatitis B surface antigen and Hepatitis C virus antibody and irregular antibodies (if any), name and address of the donor with particulars, utilisation issue number, components prepared or discarded and signature of the Medical Officer Incharge.

(3) Issue register : It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion.

(4) Records of components supplied: quantity supplied; compatibility report, details of recipient and signature of issuing person.

(5) Records of A.C.D./C.P.D/CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply, and results of testing.

(6) Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.

(7) Blood bank must issue the cross matching report of the blood to the patient together with the blood unit.

(8) Transfusion adverse reaction records.

(9) Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.

NOTE: The above said records shall be kept by the licensee for a period of five years.

M. **LABELS:**

The labels on every bag containing blood and/or component shall contain the following particulars, namely:

(1) The proper name of the product in a prominent place and in bold letters on the bag.
(2) Name and address of the blood bank
(3) Licence number
(4) Serial number
(5) The date on which the blood is drawn and the date of expiry as prescribed under Schedule P to these rules.
(6) A colored label shall be put on every bag containing blood. The following color scheme for the said labels shall be used for different groups of blood:

Blood Group	Color of the label
O	Blue
A	Yellow
B	Pink
AB	White

(7) The results of the tests for Hepatitis B surface antigen, and Hepatitis C virus antibody, syphilis, freedom from HIV I and HIV II antibodies and malarial parasite.
(8) The Rh group.
(9) Total volume of blood, the preparation of blood, nature and percentage of anti-coagulant.
(10) Keep continuously temperature at 2 degree centigrade to 6 degree centigrade for whole human blood and/or components as contained under III of Part XII B.

(11) Disposable transfusion sets with filter shall be used in administration equipment.
(12) Appropriate compatible cross matched blood without a typical antibody in recipient shall be used.
{13) The contents of the bag shall not be used if there is any visible evidence of deterioration 1ike haemolysis, clotting or discoloration.
(14) The label shall indicate the appropriate donor classification like "Voluntary Donor" or "Replacement Donor" in no less prominence than the proper name.

NOTES:
1.ln the case of blood components, particulars of the blood from which such components have been prepared shall be given against item numbers (5), (7),(8), (9) and (14).
2. The blood and/or its components shall be distributed on the prescription of a Registered Medical Practitioner .

Ill. PROCESSING OF BLOOD COMPONENTS FROM WHOLE BLOOD BY A BLOOD BANK

The Blood components shall be prepared by blood banks as a part of the Blood Bank services. The conditions for grant or renewal of licence to prepare blood components shall be as follows: -

(A) ACCOMMODATION :

(1) Rooms with adequate area and other specifications, for preparing blood components depending on quantum of work load shall be as specified in item B under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part.
(2) Preparation of Blood components shall be carried out only under closed system using single, double, triple or quadruple plastic bags except for preparation of Red Blood Cells Concentrates, where single bags may be used with transfer bags.

(B) EQUIPMENT :

(i) Air conditioner;
(ii) Laminar air flow bench;
(iii) Suitable refrigerated centrifuge;
(iv) Plasma expresser;
(v) Clipper and clips and or dielectric sealer;
(vi) Weighing device;
(vii) Dry rubber balancing material;
(viii) Artery forceps, scissors;
(ix) Refrigerator maintaining a temperature between 2 degree centigrade to 6 degree centigrade, a digital dial thermometer with recording thermograph and alarm device, with provision for continuous power supply;

(x) Platelet agitator with incubator (wherever necessary)

(xi) Deep freezers maintaining a temperature between minus 30 degree centigrade to minus 40 degree centigrade and minus 75 degree centigrade to minus 80 degree centigrade;

(xii) Refrigerated Water bath for Plasma Thawing;

(xiii) Insulated blood bag containers with provisions for storing at appropriate temperature for transport purposes:

(C) PERSONNEL:

The whole time competent technical staff meant for processing of Blood Components (that is Medical Officer, Technical Supervisor, Blood Bank Technician and Registered Nurse) shall be as specified in item C, under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part.

(D) TESTING FACILITIES:

General: Facilities for A,B, AB and O groups and Rh(D) grouping.

Hepatitis: B Surface antigen and Hepatitis C virus antibody, VDRL, HIV I and HIV II antibodies and malarial parasites shall be mandatory for every blood unit before it is used for the preparation of blood components. The results of such testing shall be indicated on the label.

(E) CATEGORIES OF BLOOD COMPONENTS:

(1) **CONCENTRATED HUMAN RED BLOOD CORPUSCLES:** The product shall be known as "Packed Red Blood Cells" that is Packed Red Blood Cells remaining after separating plasma from human blood.

General Requirements :

(a) Storage: Immediately after processing, the Packed Red Blood Cells shall be kept at a temperature maintained between 2 degree centigrade to 6 degree centigrade.

(b) Inspection: The component shall be inspected immediately after separation of the plasma, during storage and again at the time of issue. The product shall not be issued if there is any abnormality in color or physical appearance or any indication of microbial contamination.

(c) Suitability of Donor: The source blood for Packed Red Blood Cells shall be obtained from a donor who meets the criteria for Blood Donation as specified in item H under the heading "I. BLOOD BANKS/BLOOD COMPONENTS" of this Part.

(d) Testing of Whole Blood: Blood from which Packed Red Blood Cells are prepared shall be tested as specified in item K relating to Testing of Whole Blood under the heading "I.BLOOD BANKS/BLOOD COMPONENTS" of this Part.

(e) Pilot samples: Pilot samples collected in integral tubing or in separate pilot tubes shall meet the following specifications:

(i) One or more pilot samples of either the original blood or of the Packed Red Blood Cells being processed shall be preserved with each unit of Packed Red Blood Cells which is issued.

(ii) Before they are filled, all pilot sample tubes shall be marked or identified so as to relate them to the donor of that unit or Packed Red Blood Cells.

(iii) Before the final container is filled or at the time the final product is prepared, the pilot sample tubes accompanying a unit of Packed Red Blood Cells, shall be attached in a tamper-proof manner that shall conspicuously identify removal and re-attachment.

(iv) All pilot sample tubes, accompanying a unit of packed red blood cells, shall be filled immediately after the blood is collected or at the time the final product is prepared, in each case, by the person who performs the collection of preparation.

(F) PROCESSING :

(i) Separation: Packed Red Blood Cells shall be separated from the whole blood,-

(a) if the whole blood is stored in ACD solution within 21days, and

(b) if the whole blood is stored in CPDA-1 solution, within 35 days, from the date of collection. Packed Red Blood Cells may be prepared either by centrifugation done in a manner that shall not tend to increase the temperature of the blood or by normal undisturbed sedimentation method. A portion of the plasma, sufficient to ensure optimal cell preservation, shall be left with the Packed Red Blood Cells.

(ii) Packed Red Blood Cells Frozen: Cryophylactic substance may be added to the Packed Red Blood Cells for extended manufacturer's storage not warmer than minus 65 degree centigrade provided the manufacturer submits data to the satisfaction of the Licensing Authority and Central Licence Approving Authority, as adequately demonstrating through in-vivo cells survival and other appropriate tests that the addition of the substance, the material used and the processing methods results in a final product meets the required standards of safety, purity and potency for Packed Red Blood Cells, and that the frozen product shall maintain those properties for the specified expiry period.

(iii) Testing: Packed Red Blood Cells shall conform to the standards as laid down in the Indian Pharmacopoeia.

(2) PLATELETS CONCENTRATES:

The product shall be known as "Platelets Concentrates" that is platelets collected from one unit of blood and re-suspended in an appropriate volume of original plasma.

General Requirements :

(i) Source:

The source material for platelets shall be platelet-rich plasma or buffy coat which may be obtained from the whole blood or by plateletpheresis.

(ii) Processing:

(a) Separation of buffy-coat or platelet-rich plasma and platelets and re-suspension of the platelets shall be in a closed system by-centrifugal method with appropriate speed, force and time.

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 degree centigrade to 24 degree centigrade. When it is to be transported from the venue of blood collection to the processing laboratory,

during such transport action, the temperature as close as possible to a range between 20 degree centigrade to 24 degree centigrade shall be ensured. The platelet concentrates shall be separated within 6 hours after the time of collection of the unit of whole blood or plasma.

(c) The time and speed of centrifugation shall be demonstrated to produce an unclamped product, without visible haemolysis, that yields a count of not less than 3.5x1010 (3.5x10 raised to the power of 10) and 4.5x1010(4.5x10 raised to the power ten) i.e. platelets per unit from a unit of 350 ml and 450 ml blood respectively. One percent of total platelets prepared shall be tested of which 75 percent of the units shall conform to the above said platelet count.

(d) The volume of original plasma used for re-suspension of the platelets shall be determined by the maintenance of the pH of not less than 6 during the storage period. The pH shall be measured on a sample of platelets which has been stored for the permissible maximum expiry period at 20 degree centigrade to 24 degree centigrade.

(d) Final containers used for platelets shall be colorless and transparent to permit visual inspection of the contents. The caps selected shall maintain a hermetic seal to prevent contamination of the contents. The container material shall not interact with the contents, under the normal conditions of the storage and use, in such a manner as to have an adverse effect upon the safety, purity, potency, or efficacy of the product. At the time of filling, the final container shall be marked or identified by number so as to relate it to the donor.

(iii) Storage:

Immediately after re-suspension, platelets shall be placed in storage not exceeding for a period 5 days, between 20 degree centigrade to 24 degree centigrade, with continuous gentleagitation of the platelet concentrates maintained throughout such storage.

(iv) Testing:

The units prepared from different donors shall be tested at the end of the storage period for -

(a) Platelet count;
(b) pH of not less than 6 measured at the storage temperature of the unit;
(c) measurement of actual plasma volume;
(d) one percent of the total platelets prepared shall be tested for sterility;
(e) the tests for functional viability of the platelets shall be done by swirling movement before issue;
(f) if the results of the testing indicate that the product does not meet the specified requirements, immediate corrective action shall be taken and records maintained.

(iv) Compatibility Test:

Compatible transfusion for the purpose of variable number of Red Blood Cells, A, B, AB and O grouping shall be done if the platelets concentrate is contaminated with red blood cells.

(3) GRANULOCYTE CONCERNTRATES:

(i) Storage: It shall be kept between 20 degree centigrade to 24 degree centigrade for a maximum period of 24 hours.

(ii) Unit of granulocytes shall not be less than 1 x1010 (i.e. 1x10 raised to the power of 10) when prepared on cell separator.

(iii) Group specific tests/HLA test wherever required shall be carried out.

(4) FRESH FROZEN PLASMA:

Plasma frozen within 6 hours after blood collection and stored at a temperature not warmer than minus 30 degree centigrade, shall be preserved for a period of not more than one year.

(5) CRYOPRECIPITATE:

Concentrate of anti-hemophiliac factor shall be prepared by thawing of the fresh plasma frozen stored at minus 30 degree centigrade.

(a) Storage:

Cryoprecipitate shall be preserved at a temperature not higher than minus 30 degree centigrade and may be preserved for a period of not more than one year from the date of collection.

(b) Activity:

Anti-hemophiliac factor activity in the final product shall be not less than 80 units per bag. One percent of the total cryoprecipitate prepared shall be tested of which seventy five percent of the unit shall conform to the said specification.

(6) PLASMAPHERESIS, PLATELETPHERESIS, LEUCAPHERESIS USING A CELL SEPARATOR.

An area of 10 square meters shall be provided for apheresis in the blood Bank. The blood banks specifically permitted to undertake the said apheresis on the donor shall observe the criteria as specified in item H relating to Criteria for blood donation under the heading "I. Blood Banks/Blood Components" of this Part. The written consent of the donor shall be taken and the donor must be explained, the hazards of apheresis. The Medical Officer shall certify that donor is fit for apheresis and it shall be carried out by a trained person under supervision of the Medical Officer.

(A) PLASMAPHERESIS, PLATELET PHERESIS AND LEUCAPHERESIS:

The donors subjected to plasmapheresis, plateletpheresis and leucopheresis shall, jn addition to the criteria specified in item H relating to the CRITERIA FOR BLOOD DONATION, under the heading "I. BLOOD BANKS/ BLOOD COMPONENTS" of this Part being observed, be also subjected to protein estimation on post-pheresis/ first sitting whose results shall be taken as a reference for subsequent Pheresis/Sitting. It shall also be necessary that the total plasma obtained from such donor and periodicity of Plasmapheresis shall be according to the standards described under validated Standard Operating Procedures.

NOTE:

(i) At least 48 hours must elapse between successive apheresis and not more than twice in a week.

(ii) Extracoporeal blood volume shall not exceed 15% of donor's estimated blood Volume.

(iii) Platelet pheresis shall not be carried out on donors who have taken medication containing Asprin within 3 days prior to donation.

(iv) If during plateletpheresis or leucapheresis, RBCs cannot be re-transfused then at least 12 weeks shall elapse before a second cytapheresis procedure is conducted.

(B) MONITORING FOR APHERESIS:

Before starting apheresis procedure. hemoglobin or haematocrit shall be done. Platelet count, WBC counts, differential count may be carried out. In repeated plasmapheresis, the serum protein shall be 6 gm /100 ml.

(C) COLLECTION OF PLASMA:

The quantity of plasma separated from the blood of a donor shall not exceed 500 ml per sitting and once in a fortnight or shall not exceed 1000 ml per month.