MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th March, 2020

G.S.R. 166(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 1152(E), dated the 29th November, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of said Official Gazette were made available to the public on the 30th November, 2018;

And whereas objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2020.

   (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in Part X B, in the heading, for the words "Blood Banks", the words "Blood Centres" shall be substituted.

3. In the said rules, in rule 122EA, in sub-rule (1),—

   (i) For clause (d) following shall be substituted, namely,—

   "(d) 'Blood Centre' is an authorized premises in an organization or institution as the case may be, for carrying out all or any of the operations including collection, apheresis, processing, storage and distribution of blood drawn from donors or received from another licensed Blood Centre and for preparation, storage and distribution of blood components;"

   (ii) In clause (g), after the word 'accepting', the words 'against donated unit' shall be inserted.

   (iii) after clause (m), the following clause shall be inserted, namely,—

   (n) 'Erythrocytapheresis' means selective collection of one or two units of red cells from a donor or patient using a cell separator and re-transfusing the remaining blood into the donor or patient."

4. In the said rules, in rule 122EA, rule 122F, rule 122G, rule 122I and rule 122P, for the words "Blood Bank", the words "Blood Centre" wherever they occur shall be substituted.

5. In the said rules, in rule 122G, in sub-rule (1), for condition (i) the following shall be substituted, namely,—

   "(i) The operation of Blood Centre or processing or both of whole human blood for components shall be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person who is whole time employee and who is Medical Officer, and possessing—

   (a) Degree in Medicine M.B.B.S. having experience of working in Blood Centre, not less than one year during regular service and also has adequate knowledge and

experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood or preparation of its components or both; or

(b) Degree in Medicine M.B.B.S. with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with six months experience in a licensed Blood Centre; or

(c) Degree in Medicine M.B.B.S. with Diploma in Transfusion Medicine or Diploma in Immunohematology or Blood Transfusion with three months experience in a licensed Blood Centre; or

(d) Doctor of Medicine Pathology or Diplomate of National Board Pathology with three months experience in a licensed Blood Centre; or

(e) Postgraduate degree in Transfusion Medicine - Doctor of Medicine Transfusion Medicine or Diplomate of National Board Transfusion Medicine, Doctor of Medicine Immunohematology and Blood Transfusion,

the degree or diploma being from a University recognized by the Central Government or State Government.

Explanation.— For the purposes of this condition, the experience in Blood Centre shall not apply in the case of persons who are approved by the Licensing Authority or Central Licence Approving Authority or both prior to the commencement of the Drugs and Cosmetics (Second Amendment) Rules, 1999.".

6. In the said rules, in rule 122G, for sub-rule (2) and Explanation thereto, the following shall be substituted, namely,—

"[(2) Applications for grant or renewal of license for operation of Blood Centre or processing of Human blood components shall be made by the Blood Centre run by the Government, Indian Red Cross Society, Hospital, Charitable Trust or Voluntary organization and Blood Centre run by Charitable Trust or Voluntary organization need to be approved by a State or Union territory Blood Transfusion Council as per procedure laid down in this regard by the National Blood Transfusion Council.

Explanation:—For the purpose of this sub-rule, "renewal" shall include renewal of any license issued after the commencement of the Drugs and Cosmetics (Sixth Amendment) Rules, 2005).]".

7. In the said rules, in Schedule A, in Form 26G, Form 27C and Form 28C, for the words "Blood Bank", the words "Blood Centre" wherever they occur shall be substituted.

8. In the said rules, in Schedule F, in Part XII B,—

(1) (a) for the words "Blood Bank", the words "Blood Centre" wherever they occur shall respectively be substituted.

(b) for the words "Blood Banks", the words "Blood Centres" wherever they occur shall respectively be substituted.

(c) for the words "Blood Banking", the words "Blood Centres" wherever they occur shall respectively be substituted.

(d) for the words "Blood Bank's", the words "Blood Centre's" shall be substituted.

(2) under the heading "I. BLOOD CENTRES/BLOOD COMPONENTS", under sub-heading "B. ACCOMMODATION FOR A BLOOD CENTRES",—

(i) for serial number (8), the following shall be inserted, namely,-

"(8) Store-cum-records;

(9) Counseling area with adequate privacy;

(10) Identified Quality Control area with component preparation area may be provided.".

(ii) under sub-heading "C. PERSONNEL"

(a) for clause (b), the following shall be substituted, namely,—

"(b) Blood Centre Technician(s) possessing—

(i) Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood and/or its components in licensed Blood Centre; or

(ii) Degree in Medical Laboratory Technology (M.L.T.) or Blood Bank Technology with six month's experience in the testing of blood and/or its components in licensed Blood Centre; or

(iii) B.Sc. in Hematology and Transfusion Medicine with six month's experience in the testing of blood and/or its components in licensed Blood Centre; or

(iv) M.Sc. in Transfusion Medicine with six month's experience in the testing of blood and/or its components in licensed Blood Centre; or

(v) Post Graduate Diploma in Medical Laboratory Technology (PGDMLT) / Post Graduate Diploma in Medical Laboratory Science (PGDMLS) with six month's experience in the testing of blood and/or its components in licensed Blood Centre."

(b) for clause (d), the following clause shall be substituted, namely:—

"(d) Technical supervisor (where blood components are manufactured), possessing—

(i) Diploma in Medical Laboratory Technology or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood or its components or both in licensed Blood Centre; or

(ii) Degree in Medical Laboratory Technology or Blood Bank Technology with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(iii) B.Sc. in Hematology and Transfusion Medicine with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(iv) M.Sc. in Transfusion Medicine with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(v) Post Graduate Diploma in Medical Laboratory Technology or Post Graduate Diploma in Medical Laboratory Science with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(vi) Post Graduate Diploma in Transfusion Technology (PGDTT) approved by the Central Government or State Government with experience of 6 months in testing of blood or its components or both in licensed blood centre."

(c) after clause (d) so amended, the following paragraph shall be inserted, namely,—

"Blood Centre organizing blood donation camps shall have following whole time or part time counseling staff (Counselor or Medical Social Worker) possessing,—

(a) Master's degree in social work, sociology, psychology with six months of experience; or

(b) Degree in Science or Health Science with one year of experience; or

(c) Person with 10+2 having three years of experience in the field of counseling in the Blood centers collecting blood less than 3000 units per annum can share counselor or medical social worker within the institution."

(iii) under sub-heading "E, EQUIPMENT", after the entry no. 15, the following entries shall be inserted, namely,—

"16. Standard Certified Weight (s)	----		Once in a year
17. Equipment for Transfusion Transmitted Infection (TTI) laboratory like ELISA Plate Reader if ELISA is used	----	Each run	Once in a year
or			
Chemiluminescence Immuno Assay (CLIA) or Enzyme Linked Fluorescence Assay (ELFA)	----	Each day of use	
18.Micropipettes if ELISA is used	----	----	Once in a year

"

(iv) For sub-heading H., the following shall be substituted, namely,—

"H. CRITERIA FOR BLOOD DONATION

S.No.	Condition	Criteria
1.	Well being	The donor shall be in good health, mentally alert and physically fit and shall not be inmates of jail or any other confinement. "Differently abled" or donor with communication and sight difficulties can donate blood provided that clear and confidential communication can be established and he/she fully understands the donation process and gives a valid consent.
2.	Age	Minimum age 18 years Maximum age 65 years First time donor shall not be over 60 years of age, for repeat donor upper limit is 65 years. For apheresis donors 18-60 years
3.	Whole Blood Volume Collected and weight of donor	350 ml- 45 kg 450ml– more than 55 kg Apheresis– 50 kg
4.	Donation Interval	For whole blood donation, once in three months (90 days) for males and four months (120 days) for females. For apheresis, at least 48 hours interval after platelet/ plasma – apheresis shall be kept (not more than 2 times a week, limited to 24 in one year)

		After whole blood donation a plateletpheresis donor shall not be accepted before 28 days. Apheresis platelet donor shall not be accepted for whole blood donation before 28 days from the last platelet donation provided reinfusion of red cell was complete in the last plateletpheresis donation. If the reinfusion of red cells was not complete then the donor shall not be accepted within 90 days. A donor shall not donate any type of donation within 12 months after a bone marrow harvest, within 6 months after a peripheral stem cell harvest.
5.	Blood Pressure	100-140mm Hg systolic 60-90 mm Hg diastolic with or without medications. There shall be no findings suggestive of end organ damage or secondary complication (cardiac, renal, eye or vascular) or history of feeling giddiness, fainting made out during history and examination. Neither the drug nor its dosage should have been altered in the last 28 days.
6.	Pulse	60- 100 Regular
7.	Temperature	Afebrile;37ºC/98.4ºF
8.	Respiration	The donor shall be free from acute respiratory disease.
9.	Haemoglobin	>or =12.5g/dL Thalassemia trait may be accepted, provided haemoglobin is acceptable.
10.	Meal	The donor shall not be fasting before the blood donation or observing fast during the period of blood donation and last meal should have been taken at least 4 hours prior to donation. Donor shall not have consumed alcohol and show signs of intoxication before the blood donation. The donor shall not be a person having regular heavy alcohol intake.
11.	Occupation	The donor who works as air crew member, long distance vehicle driver, either above sea level or below sea level or in emergency services or where strenuous work is required, shall not donate blood at least 24 hours prior to their next duty shift. The donor shall not be a night shift workers without adequate sleep.
12.	Risk behaviour	The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination. The donor shall not be a person considered “at risk” for HIV, Hepatitis B or C infections (Transgender, Men who have sex with men, Female sex workers, Injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood).
13.	Travel and residence	The donor shall not be a person with history of residence or travel in a geographical area which is endemic for diseases that can be transmitted by blood transfusion and for which screening is not mandated or there is no guidance in India.

14.	Donor Skin	The donor shall be free from any skin diseases at the site of phlebotomy. The arms and forearms of the donor shall be free of skin punctures of scars indicative of professional blood donors or addiction of self-injected narcotics.
Physiological Status for Women		
15.	Pregnancy or recently delivered	Defer for 12 Months after delivery
16.	Abortion	Defer for 6 months after abortion
17.	Breast feeding	Defer for total period of lactation
18.	Menstruation	Defer for the period of menstruation
Non-specific illness		
19.	Minor non-specific symptoms including but not limited to general malaise, pain, headache	Defer until all symptoms subside and donor is afebrile
Respiratory (Lung) Diseases		
20.	Cold, flu, cough, sore throat or acute sinusitis	Defer until all symptoms subside and donor is afebrile
21.	Chronic sinusitis	Accept unless on antibiotics
22.	Asthmatic attack	Permanently Defer
23.	Asthmatics on steroids	Permanently Defer
Surgical Procedures		
24.	Major surgery	Defer for 12 months after recovery. (Major surgery being defined as that requiring hospitalisation, anaesthesia (general/spinal) had Blood Transfusion and/or had significant Blood loss)
25.	Minor surgery	Defer for 6 months after recovery
26.	Received Blood Transfusion	Defer for 12 months
27.	Open heart surgery Including By-pass surgery	Permanently defer
28.	Cancer surgery	Permanently defer
29.	Tooth extraction	Defer for 6 months after tooth extraction
30.	Dental surgery under anaesthesia	Defer for 6 months after recovery
Cardio-Vascular Diseases (Heart Disease)		
31.	Has any active symptom (Chest Pain, Shortness of breath, swelling of feet)	Permanently defer
32.	Myocardial infarction (Heart Attack)	Permanently defer
33.	Cardiac medication (digitalis, nitro-glycerine)	Permanently defer
34.	Hypertensive heart disease	Permanently defer
35.	Coronary artery disease	Permanently defer
36.	Angina pectoris	Permanently defer
37.	Rheumatic heart disease with residual damage	Permanently defer

Central Nervous System/ Psychiatric Diseases		
38.	Migraine	Accept if not severe and occurs at a frequency of less than once a week
40.	Convulsions and Epilepsy	Permanently defer
41.	Schizophrenia	Permanently defer
42.	Anxiety and mood disorders	Accept person having anxiety and mood (affective) disorders like depression or bipolar disorder, but is stable and feeling well on the day regardless of medication-
Endocrine Disorders		
43.	Diabetes	Accept person with Diabetes Mellitus well controlled by diet or oral hypoglycaemic medication, with no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease (in particular peripheral ulceration) - Permanently defer person requiring insulin and/or complications of Diabetes with multi organ involvement- Defer if oral hypoglycaemic medication has been altered/dosage adjusted in last 4 weeks
44.	Thyroid disorders	Accept donations from individuals with Benign Thyroid Disorders if euthyroid (Asymptomatic Goitre, History of Viral Thyroiditis, Auto Immune Hypo Thyroidism) Defer if under investigation for Thyroid Disease or thyroid status is not known Permanently defer if: 1) Thyrotoxicosis due to Graves' Disease 2) Hyper/Hypo Thyroid 3) History of malignant thyroid tumours
45.	Other endocrine disorders	Permanently defer
Liver Diseases and Hepatitis infection		
46.	Hepatitis	Known Hepatitis B, C - Permanently defer Unknown Hepatitis - Permanently defer Known hepatitis A or E -Defer for 12 months
47.	Spouse/ partner/ close contact of individual suffering with hepatitis,	Defer for 12 months
48.	At risk for hepatitis by tattoos, acupuncture or body piercing, scarification and any other invasive cosmetic procedure by self or spouse/ partner	Defer for 12 months
49.	Spouse/ partner of individual receiving transfusion of blood/ components	Defer for 12 months
50.	Jaundice	Accept donor with history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in neonatal period.
51.	Chronic Liver disease/Liver Failure	Permanently defer

HIV Infection/AIDS		
52.	At risk for HIV infection (Transgender, Men who have Sex with Men, Female Sex Workers, Injecting drug users, persons with multiple sex partners)	Permanently defer
53.	Known HIV positive person or spouse/ partner of PLHA (person living with HIV AIDS)	Permanently defer
54.	Persons having symptoms suggestive of AIDS	Permanently defer person having lymphadenopathy, prolonged and repeated fever, prolonged & repeated diarrhoea irrespective of HIV risk or status
Sexually Transmitted Infections		
55	Syphilis (Genital sore, or generalized skin rashes)	Permanently defer
56.	Gonorrhoea	Permanently defer
Other Infectious diseases		
57.	History of Measles, Mumps, Chickenpox	Defer for 2 weeks following full recovery
58.	Malaria	Defer for 3 months following full recovery.
59.	Typhoid	Defer for 12 Months following full recovery
60.	Dengue/ Chikungunya	In case of history of Dengue/Chikungunya: Defer for 6 Months following full recovery. Following visit to Dengue/Chikungunya endemic area: 4 weeks following return from visit to dengue endemic area if no febrile illness is noted.
61.	Zika Virus/ West Nile Virus	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area orZika virus outbreak zone: Defer for 4 months.
62.	Tuberculosis	Defer for 2 years following confirmation of cure
63.	Leishmaniasis	Permanently defer
64.	Leprosy	Permanently defer
Other infections		
65.	Conjunctivitis	Defer for the period of illness and continuation of local medication.
66.	Osteomyelitis	Defer for 2 years following completion of treatment and cure.
Kidney Disease		
67.	Acute infection of kidney (pyelonephritis)	Defer for 6 months after complete recovery and last dose of medication
68.	Acute infection of bladder (cystitis) / UTI	Defer for 2 weeks after complete recovery and last dose of medication
69.	Chronic infection of kidney/ kidney disease/ renal failure	Permanently defer

Digestive System		
70.	Diarrhoea	Person having history of diarrhoea in preceding week particularly if associated with fever: Defer for2 weeks after complete recovery and last dose of medication
71.	GI endoscopy	Defer for 12 months.
72.	Acid Peptic disease	Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal reflux disorder (GERD), hiatus hernia: Permanently defer person with stomach ulcer with symptoms or with recurrent bleeding:
Other diseases/ disorders		
73.	Autoimmune disorders like Systemic lupus erythematosis, scleroderma, dermatomyositis, ankylosing spondylitis or severe rheumatoid arthritis	Permanently defer
74.	Polycythaemia Vera	Permanently defer
75.	Bleeding disorders and unexplained bleeding tendency	Permanently defer
76.	Malignancy	Permanently defer
77.	Severe allergic disorders	Permanently defer
78.	Haemoglobinopathies and red cell enzyme deficiencies with known history of haemolysis	Permanently defer
Vaccination and inoculation		
79.	**Non live vaccines and Toxoid:** Typhoid,Cholera,Papillomavirus, Influenza,Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague	Defer for 14 days
80.	**Live attenuated vaccines**: Polio oral,Measles(rubella) Mumps, Yellow fever, Japanese encephalitis, influenza,Typhoid,Cholera,Hepatitis A	Defer for 28 days
81.	Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum	Defer for 28 days
82.	Anti-rabies vaccination following animal bite, Hepatitis B Immunoglobulin, Immunoglobulins	Defer for 1 year
83.	Swine Flu	Defer for 15 days
Medications taken by prospective blood donor		
84.	Oral contraceptive	Accept
85.	Analgesics	Accept
86.	Vitamins	Accept

87.	Mild sedative and tranquillizers	Accept
88.	Allopurinol	Accept
89.	Cholesterol lowering medication	Accept
90.	Salicylates (aspirin), other NSAIDs	Defer for 3 days if blood is to be used for Platelet preparation
91.	Ketoconazole, Antihelminthic drugs including mebendazole,	Defer for 7 days after last dose if donor is well
92.	Antibiotics	Defer for 2 Weeks after last dose if donor is well
93.	Ticlopidine, clopidogrel	Defer for 2 Weeks after last dose
94.	Piroxicam, dipyridamole	Defer for 2 Weeks after last dose
95.	Etretinate, Acitretin or Isotretinoin. (Used for acne)	Defer for 1 month after the last dose
96.	Finasteride used to treat benign prostatatic hyperplasia	Defer for 1 month after the last dose
97.	Radioactive contrast material	8 weeks deferral
98.	Dutasteride used to treat benign prostatatic hyperplasia	Defer for 6 months after the last dose
99.	Any medication of unknown nature	Defer till details are available
100.	Oral anti-diabetic drugs	Accept if there is no alteration in dose within last 4 weeks.
101.	Insulin	Permanently defer
102.	Anti-arrhythmic, Anti-convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs (Digitalis)	Permanently defer
Other conditions requiring Permanent deferral		
103.	Recipients of organ, stem cell and tissue transplants Donors who have had an unexplained delayed faint or delayed faint with injury or two consecutive faints following a blood donation.	Permanently defer
Residents of other countries		
104	Residents of other countries	Accept only after stay in India for three continuous years

(3) under the heading "II. BLOOD DONATION CAMPS",—

(i) in "Notes", at serial number (i), after the words "constituted by a State Government" the following words shall be inserted, namely,—

"in accordance with procedure laid down by the National Blood Transfusion Council in this regard"

(ii) under the sub-heading "(B) Personnel for Out-door Blood Donation Camp", for serial number (ii), the following shall be substituted, namely,—

"(ii) two counselors or medical social workers;"

(iii) under sub-heading "(C) Equipments", for item 12, the following shall be substituted, namely,—

"12. Portable Hb meter or copper sulphate method or any quantitative method can be used for determination of Hemoglobin estimation."

(4) under the heading "III. Processing of Blood Components from Whole Blood by a Blood Centre",

(i) under sub-heading "(B) Equipment",—

(a) for item (iv), the following shall be substituted, namely,—

"(iv) Plasma Expresser or Automated Extractor or Multi Head Tube Sealer;";

(b) for item (xi), the following shall be substituted, namely,—

"(xi) Deep Freezer or Snap Freezer maintaining a temperature between minus 30 degree centigrade to minus 40 degree centigrade and minus 75 degree centigrade to minus 80 degree centigrade;";

(c) after item (xiii), the following shall be inserted, namely,— "(xiv) Cryobath and any better equipment or technology.".

(ii) under sub-heading "(E) Categories of Blood Components",—

(a) in clause (1), for the portion beginning with the words "The product shall be'' and ending with the words "from human blood.", the following shall be substituted, namely,—

"The product shall be known as "Packed Red Blood Cells" that is packed red blood cells remaining after separating plasma from human blood which also include modified packed red blood cells including semi-packed red blood cells, washed red blood cells, leukoreduced red blood cells, irradiated red blood cells and frozen red blood cells.

Types of Red Cell components:—

(i) Saline washed Red Cells: Red cells washed with sterile Normal Saline by centrifugation at 2 to 8 degrees centigrade

(ii) Leucodepleted red cells: Shall be prepared by a method known to reduce leucocytes in the final component to less than $5x10^8$ when intended to prevent febrile reactions and to less than $5x10^6$ when required to prevent alloimmunisation or cytomegalovirus infection. For achieving a level of less than $5x10^6$ leucocyte filters are necessary.

(iii) Irradiated red cells: prepared by gamma cell or x-irradiation at 25 Gy to prevent graft versus host disease due to proliferation of lymphocytes.

(iv) Frozen Packed Red Blood Cells: Cryoprotective substance may be added to the Packed Red Blood Cells for extended storage between minus 80 to minus 196 degrees centigrade.

(v) Packed red cell aliquot prepared for transfusion to paediatric patients by technique to preserve sterility.

The quality control criteria for validation of the processes should be as follows:

1% of Packed Red cells may be tested of which at-least 75% of the packed red cells shall conform to following quality control criteria-

(a) Volume:

250 ml +/- 10% from 450 ml bag

150 ml+/- 10% from 350 ml bag

(b) Hematocrit:

65-70% when stored in CPDA1 solution

50-60% when stored in SAGM solution

(c) Culture:

Sterile"

(b) in clause (2) relating to the Platelets Concentrates, after first paragraph, the following shall be inserted, namely,—

"Types of Platelets:—

i. Platelet Rich Plasma: plasma which is rich in platelets and separated from whole blood

ii. Random Donor Platelet Concentrate

(a) prepared from platelet rich plasma

(b) prepared from Buffy Coat

iii. Pooled Platelets

(a) prepared by pooling of 6 units of random donor platelet, preferably ABO or Rh type matched are pooled into one bag of "Pooled Platelets"."

(c) in clause (2), after sub-clause (v) relating to compatibility tests, the following shall be inserted, namely,—

"Preparation of pooled platelet concentrate:—

One single unit of random donor platelets is not enough to provide adequate haemostatic dose in an adult patient. Therefore, up to 6 units of random donor platelets, preferably ABO or Rh type matched are pooled into one bag of "Pooled Platelet Concentrate". The pooled platelets may be prepared by pooling buffy coats and then processed into one unit of pooled buffy coats— pooled platelet concentrate. Alternatively, pooling can be done after preparation of random donor platelets by platelet rich plasma method or buffy coat method. If the pooling is done in an open system (using spikes for pooling), the shelf life of the pooled platelets will be 6 hours, while for closed system (using sterile connecting device) the expiry date will be that of the platelet unit having the shortest expiry date. The labeling requirements for the final pooled product shall remain same as any other platelet product except that the final pack should have a unique pool number or donation numbers of all contributing units.

The platelet content in the pooled product should be $\geq$ 2 X 1011/unit. Modified platelet component includes: leucodepleted, irradiated, washed platelets or platelets suspended in additive solution."

(d) in clause (3) relating to Granulocyte Concentrates, for sub-clause (i) and (ii), the following sub-clauses shall be substituted, namely,—

"(i) Granulocyte concentrates is prepared either by pooling multiple units of buffy coat or by apheresis as described under apheresis section. The same shall be stored at 20-24ºC and used within a maximum period of 24 hours.

(ii) Pooled granulocytes shall meet the same Quality Control requirements as that for apheresis granulocytes. (at least 1 x 10 raised to the power 10).".

(e) in clause (4) relating to Fresh Frozen Plasma, after first paragraph, the following shall be inserted, namely,—

"The quality control criteria for validation of the processes should be as follows:

Volume:

180-220 ml from 350 ml bag

220-300 ml from 450 ml bag

Factor VIII: at least 70 iu / bag

Excess and expired plasma may be issued for fractionation to the licensed fractionation centre in the Country with justification to be recorded in writing."

(f) in clause (5), for the words "Concentrate of anti-hemophiliac factor shall be prepared by thawing of the fresh plasma frozen stored at minus 30 degree centigrade", the following shall be substituted, namely:—

"Concentrate of anti-hemophiliac factor shall be prepared by thawing FFP at 4ºC in a cold room or blood bank refrigerator or 4-10ºC in a cryobath. Minus 80ºC deep freezer should be used for faster freezing of plasma for preparation of cryoprecipitate.

The quality control criteria for validation of the processes should be as follows:

Volume: 15 – 20 ml

Fibrinogen: at least 150 mg/bag

Factor VIII: at least 80 iu/bag

Preparation of pooled cryoprecipitate:

One single unit of cryoprecipitate is not enough to provide adequate haemostatic dose in an adult patient. Therefore, multiple units of cryoprecipitate may be pooled in one bag. If the pooling is done in an open system (using spikes for pooling), the shelf life of the pooled cryoprecipitate will be 6 hours.

The labeling requirements for the final pooled product shall remain same as any other cryoprecipitate product except that the final pack should have a unique pool number or donation numbers of all contributing units."

(5) for sub-heading "F. Plasmapheresis, Plateletpheresis, Leucapheresis, Using a Cell Separator", the following shall be substituted, namely,—

"**(F) APHERESIS USING A CELL SEPARATOR**

General requirements:

(a) Accommodation: An air-conditioned area of 10 square meters shall be provided for apheresis/therapeutic procedures in the blood Centre.

(b) Equipment:

i. Cell separator
ii. Dielectric tube sealer
iii. Other emergency equipments/ items

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

(c) Criteria for selection of donors:

At least 48 hours must elapse between successive apheresis and not more than twice in a week. For haematopoietic stem cells the procedures can be done daily.

Types of Apheresis:

1. Plasmapheresis
2. Plateletpheresis for harvesting Platelet concentrate (Single Donor Platelets)
3. Leucapheresis for harvesting
   - Granulocyte concentrate
   - Lymphocytes
   - Mononuclear cells
4. Erythrocytapheresis- Red cell apheresis including double unit red cell collection
5. Haematopoietic stem cells (Peripheral Blood Stem Cells)

1. Plasmapheresis:

The total serum protein shall be 6 gm/dl before the first plasmapheresis procedure.

In repeated plasmapheresis:

a. It should be tested before the third procedure if done within four weeks and it shall be 6 gm/dl.
b. The quantity of plasma separated from the blood of donor shall not exceed 500 ml per sitting and once in a fortnight or shall not exceed 1000 ml per month.

2. Plateletpheresis (Single Donor Platelets):

(i) Plateletpheresis shall not be carried out on donors who have taken medication containing aspirin within 3 days prior to donation

(ii) Platelet count, WBC counts, differential count may be carried out.

The term plateletpheresis includes platelets collected by apheresis, using a cell separator and the product is called single donor platelets and includes washed single donor platelets, Modified single donor platelets (with replacement of compatible plasma), leukoreduced single donor platelets and double single donor platelets collected from single donor. Single single donor platelets should have a platelet count of $\geq 3X\ 10^{11}$ / unit.

i. Storage: Shall be kept up to 5 days between 20ºC to 24ºC with continuous agitation.
ii. Apheresis platelet concentrates should contain minimum of 3×10^{11} platelets in 75% of the units tested amongst 1% of monthly production or 4 platelet concentrates per month, whichever is higher.
iii. The pH must be 6 or higher at the end of permissible storage period.

3. Leucapheresis

This procedure includes collection of Granulocytes (Granulocytopheresis), Lymphocytes or Peripheral blood stem cells or Haematopoietic stem cells for treatment of traditional conditions followed by their preservation.

4. Erythropheresis

This is the collection of 2 units of Red cells from a single donor meeting specified requirements.

5. Therapeutic Plasmapheresis and Cytapheresis:

Therapeutic Apheresis activity is allowed in the Blood Centre attached to the Hospital having Apheresis facilities under the responsibility of Registered Medical Practitioner (RMP) who has obtained the consent of patient and record of which shall be maintained and signed by the RMP & blood bank medical officer.

This shall be done only at the written request of the patient's physician. Patient's informed consent shall be taken. Records of the procedure shall be maintained. Provisions for emergency care shall be available by the patient's physician."

9. In the said rules, in Schedule K, in Serial Number 5B and in Serial Number 30, for the words "Blood Bank", the words "Blood Centre" wherever they occur shall be substituted.

[F. No.X.11014/34/2018-DR]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The principal rules were published in the Official Gazette vide notification number F.28-10/45-H (1), dated 21st December 1945 and last amended vide notification number G.S.R. 101(E), dated the 11th February, 2020.

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