GOVERNMENT OF INDIA

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

THE DRUGS AND COSMETICS ACT AND RULES

THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

(As amended up to the 31st December, 2016)

and

THE DRUGS AND COSMETICS RULES, 1945

(As amended up to the 31st December, 2016)

[1][PART XB

REQUIREMENTS FOR THE COLLECTION, STORAGE, PROCESSING AND DISTRIBUTION OF WHOLE HUMAN BLOOD, HUMAN BLOOD COMPONENTS BY BLOOD BANKS ANDMANUFACTURE OF BLOOD PRODUCTS

[2][**122EA**. ***Definitions.***- (1) In this Part and in the Forms contained in Schedule A and in Part XII-B, [3][Part XII-C and Part XIID] of Schedule F, unless there is anything repugnant in the subject or context−

(a) "apheresis" means the process by which blood drawn from a donor, after separating plasma or platelets, or leucocytes, is re-transfused simultaneously into the said donor;

(b) "autologous blood" means the blood drawn from the patient for re-transfusion unto himself later on;

(c) "blood" means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant;

(d) "blood bank" means a place or organization or unit or institution or other arrangements made by such organization, unit or institution for carrying out all or any of the operations for collection, apheresis, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components;

(e) "blood component" means a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor;

(f) "blood product" means a drug manufactured or obtained from pooled plasma of blood by fractionation, drawn from donors;

[4][(fa) "cord blood bank" means a place or organization or unit for carrying out and responsible for operations of collection, processing, testing, banking, selection and release of cord blood units;]

(g) "donor" means a person who voluntarily donates blood after he has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or in kind from any source but does not include a professional or a paid donor.

Explanation.- For the purposes of this clause, benefits or incentives like pins, plaques, badges, medals, commendation certificates, time-off from work, membership of blood assurance programme, gifts of little or intrinsic monetary value shall not be construed as consideration;

(h) "leucapheresis" means the process by which the blood drawn from a donor, after leucocyte concentrates have been separarated is re-transfused simultaneously into the said donor;

(i) "plasmapheresis" means the process by which the blood drawn from a donor, after plasma has been separated, is re-transfused during the same sitting into the said donor;

(j) "plateletpheresis" means the process by which the blood drawn from a donor, after platelet concentrates have been separated, is re-transfused simultaneously into the said donor;

(k) "professional donor" means a person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient-patient and includes a paid donor or a commercial donor;

(l) "replacement donor" means a donor who is a family friend or a relative of the patient-recipient.]

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1. Ins. by G.S.R. 28(E), dt. 22-1-1993.
2. Ins. by G.S.R. 245 (E), dt. 5-04-1999.
3. Subs. by G.S.R. 899 (E), dt. 27-12-2011.
4. Ins. by G.S.R. 899 (E), dt. 27-12-2011.

[4][(m) "umbilical cord blood" is the whole blood including Hematopoietic Progenitor Cells collected from placental and or Umbilical cord blood vessels after the umbilical cord have been clamped.]

122-F. ***Form of application for licence for operation of Blood Bank/processing of whole human blood for components/manufacture of blood products for sale or distribution [4], collection, processing, testing, storage, banking and release of umbilical cord blood stem cells.]-*** (1) Application for the grant and/or renewal of licence for the operation of a Blood Bank/processing of human blood for components/manufacture of blood products [4] [collection, processing, testing, storage, banking and release of umbilical cord blood stem cells] shall be made to the Licensing Authority appointed under Part VII in [1][Form 27-C or [5][Form 27-E or Form 27-F], as the case may be], and shall be accompanied by [3][licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every inspection thereof or for the purpose of renewal of licence]:

Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry the fee payable for the renewal of the licence [3][shall be rupees six thousand and inspection fee of rupees one thousand and five hundred plus an additional fee at the rate of rupees one thousand per month or a part thereof in addition to the inspection fee]:

[5][Provided further that a licensee holding a license in Form 28-C, Form 28-E or Form 28-F as the case may be, for operation of Blood Bank/ processing of whole human blood for components / manufacture of blood products / collection, processing testing storage, banking and release of umbilical cord blood stem cells shall apply for grant of license under sub Rule (1) before the expiry of the said license in Form 27-C, Form 27-E or Form 27-F as the case may be and he shall continue to operate the same till the orders on his application are communicated to him.]

[2][***]

(2) A fee of [3][rupees one thousand] shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

(3) Application by a licensee to manufacture additional drugs listed in the application shall be accompanied by a fee of [3][rupees three hundred] for each drug listed in the application.

(4) On receipt of the application for the grant or renewal of such licence, the Licensing Authority shall,–

(i) verify the statements made in the application form;

(ii) cause the manufacturing and testing establishment to be inspected in accordance with the provision of rule 122-I; and

(iii) in case the application is for renewal of licence, call for information of past performance of the licensee.

(5) If the Licensing Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in the rules, he shall prepare a report to that effect and forward it [6][along with the application and the licence (in triplicate) to be granted or renewed, duly completed] to the Central Licence Approving Authority:

Provided that if the Licensing Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules, he may, by order, for reasons to be recorded in writing, refuse to grant or renew the licence, as the case may be.

(6) If, on receipt of the application and report of the Licensing Authority referred to in sub-rule [7][(5)] and after taking such measures including inspection of the premises by the Inspector, appointed by the Central Government under section 21 of the Act, and/or along

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1. Subs. by G.S.R. 245(E), dt. 5.4.1999.
2. Explanation omitted by G.S.R. 733 (E), dt. 21.12.2005 earlier Ins. by G.S.R. 89(E), dt. 14-2-1996.
3. Subs. by G.S.R. 601(E), dt. 24-8-2001.
4. Ins. by G.S.R. 899 (E), dt. 27-12-2011.
5. Subs. by G.S.R. 899 (E), dt. 27-12-2011.
6. Ins. by G.S.R. 89 (E), dt. 14.2.1996.
7. Corrected by corrigendum G.S.R. 447 (E), dt. 10-06-1993.

with the Expert in the field concerned if deemed necessary, the Central Licence Approving Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in these rules, he may grant or renew the licence, as the case may be:

Provided that if the Central Licence Approving Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules he may, notwithstanding the report of the Licensing Authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of licence, as the case may be, and shall supply the applicant with a copy of the inspection report.

122G. ***Form of Licence for the operation of a Blood Bank/processing of whole human blood for components and manufacture of blood products [3]/manufacture of blood products/collection, processing, testing, storage, banking and release of umbilical cord blood stem cells] and the conditions for the grant or renewal of such licence.***— [2][(1)] A licence for the operation of a Blood Bank or for processing whole human blood for components and [3][/manufacture of blood products/collection, processing, testing, storage, banking and release of umbilical cord blood stem cells] shall be issued in [1][Form 28C or Form 28E or [3][Form 28F or Form 26G or Form26-I or Form 26J, as the case may be, before a license in Form 28C or Form 28E or Form28-F or Form 26G or Form 26-I or Form 26-J], as the case may be,] is granted or renewed the following conditions shall be complied with by the applicant:-

[1][(i) The operation of Blood Bank and/or processing 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) Postgraduate degree in Medicine - M.D (Pathology/Transfusion Medicines); or

(b) Degree in Medicine (M.B.B.S.) with Diploma in Pathology or Transfusion Medicines having adequate knowledge in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components; or

(c) Degree in Medicine (M.B.B.S.) having experience in Blood Bank for 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 and/or preparation of its components,

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

Explanation.- For the purposes of this condition, the experience in Blood Bank for one year shall not apply in the case of persons who are approved by the Licensing Authority and/or Central Licence Approving Authority prior to the commencement of the Drugs and Cosmetics (Second Amendment) Rules, 1999].

(ii) The applicant shall provide adequate space, plant and equipment for any or all the operations of blood collection or blood processing. The space, plant and equipment required for various operation is given in Schedule 'F', Part XIIB and/or XIIC [4][or XIID].

(iii) The applicant shall provide and maintain adequate technical staff as specified in Schedule F, Part XIIB and/or XIIC [4][or XIID].

(iv) The applicant shall provide adequate arrangements for storage of whole human blood, human blood components and blood products.

(v) The applicant shall furnish to the Licensing Authority, if required to do so, data on the stability of whole human blood, its components or blood products which are likely to deteriorate, for fixing the date of expiry which shall be printed on the labels of such products on the basis of the data so furnished.

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1. Ins. by GSR 245(E), dt. 5-4-1999.
2. Renumbered as sub-rule (1) by GSR 733(E), dt. 21-12-2005.
3. Subs. by GSR 899(E), dt. 27-12-2011.
4. Ins. by GSR 899(E), dt. 27-12-2011.

[3][(2) Application for grant or renewal of a licence for operation of Blood Bank or processing of human blood components shall be made by the Blood Bank run by the Government, Indian Red Cross Society, hospital, charitable trust or voluntary organization approved by a State/ Union Territory Blood Transfusion Council only.

Explanation.– For the purpose of this sub-rule, "renewal" shall include renewal of any licenceissued prior to the commencement of the Drugs and Cosmetics (……..Amendment) Rules,2005.]

122H. ***Duration of licence.***- An original licence in [1][Form 28C or Form 28E [4][or Form 28F] or a renewed licence in Form 26G or Form 26-I] [4][or Form 26J] unless sooner suspended or cancelled shall be [2][valid for a period of five years on and from the date on which] it is granted or renewed.

122-I. ***Inspection before grant or renewal of licence for operation of Blood Bank, processing of whole human blood for components and manufacture of blood products.***- Before a licence in [1][Form 28C or Form 28E [4][or Form 28F] is granted or a renewal of licence in form 26G or Form 26-I [4][or Form 26J] is made, as the case may be,] the Licensing Authority or the Central Licence Approving Authority, as the case may be, shall cause the establishment in which Blood Bank is proposed to be operated/whole human blood for components is processed/ blood products are manufactured to be inspected by one or more Inspectors, appointed under the Act and/or along with the Expert in the field concerned. The Inspector or Inspectors shall examine all portions of the premises and appliances/equipments and inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for operation of blood bank/processing of whole human blood for components/manufacture of blood products together with their testing facilities and also enquire into the professional qualification of the expert staff and other technical staff to be employed.

122J. ***Report by Inspector.***-The Inspector or Inspectors shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendation in accordance with the provisions of rule 122-I to the Licensing Authority or to the Central Licence Approving Authority.

122K. ***Further application after rejection.***- If within a period of six months from the rejection of application of a licence the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection [2][fee of rupees two hundred and fifty] the Licensing Authority may, if after causing further inspection to be made is satisfied that the conditions for the [1][grant or renewal of a licence have been complied with, shall grant or renew the licence in Form 28C or Form 28E [4][or Form 28F]:

Provided that in the case of a drug notified by the Central Government under rule 68-A, the application, together with the inspection report and the Form of licence (in triplicate to be granted or renewed), duly completed shall be sent, to the Central Licence Approving Authority, who may approve the same and return it to the Licensing Authority for issue of the licence.]

122L. ***Delegation of powers by the Central Licence Approving Authority.***- The Central Licence Approving Authority may, with the approval of the Central Government, by notification delegate his powers of signing licences and any other power under rules to persons under his control having same qualifications as prescribed for Controlling Authority under rule 50-A, for such areas and for such periods as may be specified.

122M. ***Provision for appeal to the State Government by a party whose licence has not been granted or renewed.***- Any person who is aggrieved by the order passed by the Licensing Authority or Central Licence Approving Authority, as the case may be, may within thirty days from the date of receipt of such order, appeal to the State Government or Central Government, as the case may be, after such enquiry into the matter as it considers necessary and after giving the said person an opportunity for representing his view in the matter may pass such order in relation thereto as it thinks fit.

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1. Ins. by G.S.R 245(E), dt. 5-4-1999.
2. Subs. by G.S.R 601(E), dt. 24-8-2001.
3. Ins. by G.S.R 733(E), dt. 21-12-2005.
4. Ins. by GSR 899(E), dt. 27-12-2011.

122-N. ***Additional information to be furnished by an applicant for licence or by a licensee to the Licensing Authority.-*** The applicant for the grant of licence or any person granted a licence under the Part shall, on demand furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation, rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matter, which may be required for the purpose of verifying the correctness of the statement made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

122-O. ***Cancellation and suspension of licences.***– (1) The Licensing Authority or Central Licence Approving Authority may for such licences granted or renewed by him after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reason thereof, cancel a licence issued under this part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates [1][or direct the licensee to stop collection, storage, processing, manufacture and distribution of the said substances and [2][thereupon order the destruction of substances and] stocks thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules thereunder.

(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1) prefer an appeal against the order to the State Government or Central Government, which shall decide the same.

122-P. ***Conditions of licence***.- [3][A licence in Form 28C, Form 28E, [4][Form 28F, Form 26G, Form 26-I or Form 28J shall be subject to the special conditions set out in Schedule F, Part XII-B and Part XII C, Part XIID,] as the case may be, which relate to the substance in respect of which the licence is granted or renewed and to the following general conditions, namely:-]

(i) (a) The licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a Blood Bank for processing whole human blood, its components and/or manufacture of blood products.

(b) The licensee shall maintain staff, premises and equipment as specified in Rule 122-G. The licensee shall maintain necessary records and registers as specified in Schedule F, Parts XII-B and XII-C.

(c) The licensee shall test in his own laboratory whole human blood, its components and blood products and maintain records and registers in respect of such tests as specified in Schedule F, Parts XIIB and XIIC [5][or XIID]. The records and register shall be maintained for a period of five years from the date of manufacture.

(d) The licensee shall maintain/preserve reference sample and supply to the Inspector the reference sample of the whole human blood collected by him in an adequate quantity to conduct all the prescribed tests. The licensee shall supply to the Inspector the reference sample for the purpose of testing.

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1. Subs. by G.S.R. 20(E), dt. 11-1-1996.
2. Ins. by (Corrigenda) G.S.R. 514 (E), dt. 6-11-1996.
3. Subs. by G.S.R. 245(E), dt. 5-4-1999.
4. Subs. by GSR 899(E), dt. 27-12-2011.
5. Ins. by GSR 899(E), dt. 27-12-2011.

(ii) The licensee shall allow an Inspector appointed under the Act to enter, with or without prior notice, any premises where the activities of the Blood Bank are being carried out for the processing of Whole Human Blood and/or Blood Products, to inspect the premises and plant and the process of manufacture and the means employed for standardizing and testing the substance.

(iii) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and rules thereunder have been observed.

(iv) The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the operation of a Blood Bank/processing of whole human blood for components and/or manufacture of blood products and any material alterations in the premises or plant used for that purpose which have been made since the date of last inspection made on behalf of the Licensing Authority before the grant of the licence.

(v) The licensee shall on request furnish to the Licensing Authority, or Central Licence Approving Authority or to such Authority as the Licensing Authority, or the Central Licence Approving Authority may direct, from any batch unit of drugs as the Licensing Authority or Central Licence Approving Authority may from time to time specify, sample of such quantity as may be considered adequate by such Authority for any examination and, if so required, also furnish full protocols of the test which have been applied.

(vi) If the Licensing Authority or the Central Licence Approving Authority so directs, the licensee shall not sell or offer for sale any batch/unit in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorizing the sales of batch/unit has been issued to him by or on behalf of the Licensing Authority or the Central Licence Approving Authority.

(vii) The licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch/unit of the substance has been found by the Licensing Authority or the Central Licence Approving Authority not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do, withdraw, from sales and so far as may in the particular circumstances of the case be practicable recall all issues already made from that batch/unit.

(viii) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Further no batch/unit manufactured under this licence shall be supplied/distributed to any person without prescription of a Registered Medical Practitioner.

(ix) The licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any Rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the Rules, these would come in force four months after publication in the Official Gazette.

(x) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and defects noticed.

(xi) The licensee shall destroy the stock of batch/unit which does not comply with standard tests in such a way that it would not spread any disease/infection by way of proper disinfection method.

[1][(xii) All bio-medical waste shall be treated, disposed of or destroyed as per the provisions of the Bio-Medical Wastes (Management and Handling) Rules, 1996.

(xiii) The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components and/or manufacture blood products from the blood drawn from such a donor.]

PART XI

EXEMPTIONS

123. The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.

PART XII

STANDARDS

[2][**124.** ***Standards of drugs***: –

(1) For drugs included in the Indian Pharmacopoeia—

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.

(b) In case the standards for identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia.

(2) For other drugs–

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the official pharmacopoeia, for the time being in force, of any country to which the drug claims to comply with,

(b) In case the standards for identity, purity and strength for drugs are not specified in the edition of such official pharmacopoeia for the time being in force, but are specified in the edition immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of such official pharmacopoeia to which the drug claims to comply with.

(c) For drugs for which standards are not included in the edition of the official pharmacopoeia, for the time being in force, of any country or in edition immediately preceding, but included in the official compendia of drug standards, namely, the British Pharmaceutical Codex or the National Formulary of the United States, for the time being in force, to which the drug claims to comply with.]

[3][**124A**. ***Standards for veterinary drugs.*** –For drugs intended for veterinary use, the standards shall be those given in the current edition for the time being in force of the [4][British Pharmacopoeia (Veterinary)].

1. Subs. by G.S.R. 245(E), dt. 5-4-1999.
2. Subs. by G.S.R. 19, dt. 15-12-1977.
3. Ins. by notification F. 1-6/62-D (SO 2889), dt. 2-7-1969.
4. Subs. by G.S.R. 647 (E), dt. 28-10-1998.