

*THE DRUGS RULES, 1945¹

[21st December, 1945]

In exercise of the powers conferred by ¹[sections 6(2), 12, 33 and 33(N)] of the Drugs ²[and Cosmetics] Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:—

PART I PRELIMINARY

1. **Short title, extent and commencement.**—(1) These Rules may be called the Drugs ³[***] Rules, 1945.

(2) They extend to the whole of India ³[***].

2. **Definitions.**—In these Rules, unless there is anything repugnant in the subject or context—

(a) "the Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940), as amended from time to time;

⁶[(aa) "biopharmaceutical classification system" means a system used to classify drugs on the basis of solubility and permeability, classified as category I-high solubility and high permeability, category II-low solubility and high permeability, category III-high solubility and low permeability, and category IV-low solubility and low permeability;] ⁷[(b) "Central Licence Approving Authority" means the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government;]

(c) "Director" means the Director of the Central Drugs Laboratory;

(d) "Form" means a Form set forth in Schedule A;

⁸[(dd) "Homoeopathic medicines" include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, *viz.*, indications dosage, dosage form (including sustained release dosage form) and route of administration. (See items (b) and (c) of Appendix VI to Schedule Y).

Explanation.—For the purpose of this rule—

¹[(i) all vaccines and Recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under rule 21;]

(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval ¹⁵³[***].]



3[PART XB
REQUIREMENTS FOR THE COLLECTION, STORAGE,
PROCESSING AND DISTRIBUTION OF WHOLE HUMAN BLOOD,
HUMAN BLOOD COMPONENTS BY ¹⁵⁴[BLOOD CENTRES] ¹⁵⁵[,
MANUFACTURE OF BLOOD PRODUCTS AND COLLECTION,
PROCESSING, TESTING, STORAGE, BANKING AND RELEASE OF
UMBILICAL CORD BLOOD STEM CELLS]

⁶[122EA. **Definitions.**—(1) In this Part and in the Form contained in Schedule A and in Part X1IB ¹⁵⁶[Part XIIC and Part XIID] of Schedule F, unless there is anything repugnant in the subject of context,—

- (a) "apheresis" means the process by which blood drawn from a donor, after separating plasma or platelets or leucocytes, is retransfused simultaneously into the said donor;
- (b) "autologous blood" means the blood drawn from the patient for retransfusion into himself later on;
- (c) "blood" means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant;

⁸[(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;]

(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;

⁹[(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 ¹⁵⁷[against donated unit] in return any consideration in cash or 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 separated, is retransfused 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 retransfused 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;

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

¹[(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.]

²[(n) 'Erythrocytapheresis' means selective collection of one or two units of red cells from a donor or patient using a cell separator and retransfusing the remaining blood into the donor or patient.]

122F. Form of application for licence for operation of ³[Blood Centre]/processing of whole human blood for components/manufacture of blood products for sale or distribution ¹⁵⁸ [, 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 ¹⁶¹[Blood Centre],/processing of human blood for components/manufacture of blood products ¹[/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 '[Form 27C ¹⁵⁹ [, Form 27E or Form 27F], as the case may be,] and shall be accompanied by ¹⁶⁰[licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every inspection thereof or for the purposes 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 ⁶[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]:

⁷[Provided further that a licensee holding a licence in Form 28C, Form 28E or Form 28F as the case may be, for operation of ¹⁶¹[Blood Centre]/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 licence under sub-rule

(1) before the expiry of the said licence on Form 27C, Form 27E or Form 27F as the case may be, and he shall continue to operate the same till the orders on his application are communicated to him.]

¹ [***]

(2) A fee of rupees ¹⁶²[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 fee of ²[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 12.2-1; and
- (iii) in case the application is for renewal of licence, call for informations 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 ¹⁶³[alongwith 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 the report of the licensing authority referred to in sub-rule ¹⁶⁴[(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 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 ¹⁶⁵[Blood Centre]/processing of whole human blood for components and ⁺⁶[/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. ¹⁶⁶[(1) A licence for the operation of a ⁵[Blood Centre] or for processing whole human blood for components and ⁺⁶[/manufacture of blood products/ collection, processing, testing, storage, banking and release of umbilical cord blood stem cells] shall be issued in ¹⁶⁷ [Form 28C or Form 28E or ¹⁶⁸[Form 28F or Form 26G or Form 26-1 or Form 26], as the case may be, before a licence in Form 28C or Form 28E or Form 28F or Form 26G or Form 26-1 or Form 26J], as the case may be] is granted or renewed the following conditions shall be complied with by the applicant:—

³[(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.]

- (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 operations is given in Schedule F, Part XIIB and/or XIIC ^a[or XIID],

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- (iii) The applicant shall provide and maintain adequate technical staff as specified in Schedule F, Part XIIB and/or XIIC ^x[or XIID].
- (iv) The applicant shall provide adequate arrangements for storage of whole human blood, human blood components and blood products.
- (v) The applicant 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.

²[(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.]

122H. Duration of licence.—An original licence in ³[Form 28C or Form 28E ¹[or Form 28F] or a renewed licence in Form 26G or Form 26-I] ¹[or Form 26J] unless sooner suspended or cancelled shall be ⁴[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 ⁵[Blood Centre], processing of whole human blood for components and manufacture of blood products.—Before a licence in ³[Form 28C or Form 28E ¹[or Form 28F] is granted or a renewal of licence in Form 26G or Form 26-I¹[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 ⁵[Blood Centre] is proposed to be operated /whole human blood for component is processed ⁶[/ blood products are manufactured to be inspected by one or more inspectors, appointed under the Act and/or alongwith 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 alongwith the means to be employed or being employed for operation of ⁵[Blood Centre]/processing of whole human blood for components/manufacture of blood products together with their ⁶[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 for a licence the applicant informs the licensing authority that the conditions laid down have been satisfied and

deposits an inspection ¹[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 ¹⁶⁹[grant or renewal of a licence have been complied with, shall grant or renew the licence in Form 28C or Form 28E ¹⁷⁰[or Form 28F]:

Provided that in the case of a drug notified by the Central Government under rule 68A, 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 be Central Licence Approving Authority, who may approve the same and return it to the licensing authority of issue for 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 licence and any other power under rules to persons under his control having same qualifications as prescribed for controlling authority under rule 50A, 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.

122N. Additional information to be furnished by an ¹⁷¹[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.

122-0. 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 by 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, ⁵[or direct the licensee to stop collection, storage, processing, manufacture and distribution of the said substances and ¹⁷²[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 provision 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 that order to the State Government or Central Government, which shall decide the same.

122P. Conditions of licence.— [A licence in Form 28C, Form 28E, ¹⁷³[Form 28F, Form 26G, Form 26-I or Form 26J shall be subject to the special conditions set out in Schedule F, Part XIIB and Part XIIC, 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 ¹⁷⁴[Blood Centre] 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 122G. The licensee shall maintain necessary records and registers as specified in Schedule F, Part XIIB and XIIC.
- (c) The licensee shall test in his own laboratory whole human blood, its components and blood products and ¹⁷⁵[maintain records and] registers in respect of such tests as specified in Schedule F, Parts XIIB and XIIC ¹⁷⁶[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 ⁴[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.

(ii) The licensee shall allow an Inspector appointed under the Act to enter, with or ⁴[without] prior notice, any premises where the activities of the ³[Blood Centre] 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 mean employed for standardising 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 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 ³[Blood Centre]/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 authorising 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 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.¹⁷⁷

(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 stocks 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.]

²[(xii) All bio-medical waste shall be treated, disposed off 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.]

³[(xiv) The whole human blood and blood components may be transferred, under prescribed storage conditions, to another blood bank which have facilities to store and monitor blood distribution.

(xv) The recipient ⁴[blood centres] shall not further transfer units obtained from another '[blood centre] except to another blood storage centre or a patient.]

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.

⁶[124. Standards of drugs.]—(1) 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, or 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