

***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

30. improvement in size and shape of the sexual organ and in duration of sexual performance
31. improvement in the strength of the natural teeth
32. Improvement in vision
33. Jaundice/Hepatitis/Liver disorders
34. Leukaemia
35. Leucoderma

SCHEDULE K

(See rule 123)

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemptions</i>
1. Drugs falling under clause (b)(i) of section 3 of the Drugs and Cosmetics Act, not intended for medicinal use.	All the provisions of Chapter IV of the Act and the rules thereunder, subject to the conditions that the drug is not sold for medicinal use or for use in the manufacture of medicines and that each container is labelled conspicuously with the words "NOT FOR MEDICINAL USE".
[2.***]	
² [2A. Quinine and other antimalarial drugs.]	³ [Persons selling the drugs by retail under arrangements made by State Government for sale and distribution of the drugs will be exempted from the requirements to take out licences for retail sale under clause (c) of section 18 of the Act.]
[3.***]	
[4.***]	
⁵ [5. Drugs supplied by a registered medical practitioner to his own patient or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the	All the provisions of Chapter IV of the Act and the rules made thereunder, subject to the following conditions:— ⁵ [(1) The drugs shall be purchased only from a dealer or a manufacturer licensed under these rules, and records of such purchases showing the names and quantities of such drugs, together with their batch numbers and names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may, if necessary, make enquiries about purchases of the drugs and may also take

rules thereunder.]

samples for test.]

(2) In the case of medicine containing a substance specified in ³⁰⁶[Schedule G, H or X] the following additional conditions shall be complied with:—

(a) the medicine shall be labelled with the name and address of the registered medical practitioner by whom it is supplied;

(b) If the medicine is for external application, it shall be labelled with the words ³⁰⁷[***] "For external use only" or, if it is for internal use with the dose;

(c) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient and the date of supply and the name of the person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose;

(d) the entry in the register shall be given a number and that number shall be entered on the label of the container;

(e) the register and the prescription, if any, on which the medicines are issued shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription, as the case may be.

²[(3) The drug will be stored under proper storage conditions as directed on the label.]

³[(4) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.]

⁴[5A. Drugs supplied by a hospital or dispensary maintained or supported Government or local body ³⁰⁸[***]

The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence, subject to the following conditions :

(1) The dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person;

(2) The premises where drugs are supplied or stocked shall be open to inspection by an Inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take samples for test;

(3) The drugs shall be stored under proper

storage conditions.

(4) 12[The drugs shall be purchased from a manufacturer or a dealer licensed under these rules or received as transferred stocks from hospital stores for distribution. Records of such purchases or receipts shall be maintained.]

(5) 13[No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.]

14[5B. Whole Human Blood IP and / or its components stored for transfusion by a First Referral Unit, Community Health Centre, Primary Health Centre and a Hospital.

The provisions of Chapter IV of the Act and the rules made thereunder which require obtaining of a licence for operation of a Blood Bank or processing Whole Human Blood and / or its components, subject to the following conditions, namely: -

(1) The First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall be approved by the State / Union Territory Licensing Authority after satisfying the conditions and facilities through inspection.

(2) [***]

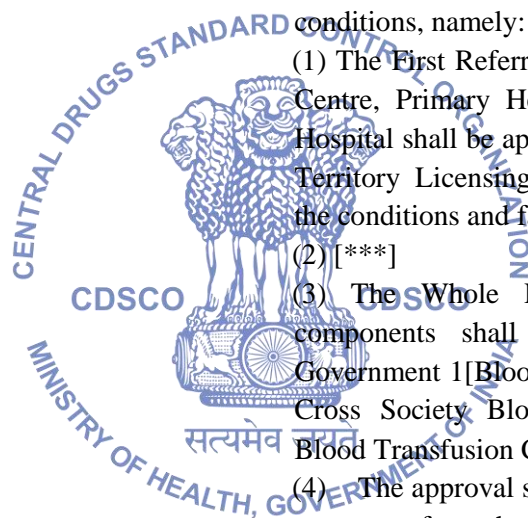
(3) The Whole Human Blood and/or its components shall be procured only from Government [Blood centre] and/or Indian Red Cross Society Blood Bank and/or Regional Blood Transfusion Centre duly licensed.

(4) The approval shall be valid for a period of two years from the date of issue unless sooner suspended or cancelled and First Referral Unit, Community Health Centre, Primary Health Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval.

(5) The First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall have the following technical staff for storage of blood or its components:—

(a) A trained Medical Officer for proper procurement, storage and cross matching of blood and/or its components. He/ she shall also be responsible for identifying haemolysed blood and ensure non-supply of date expired blood or its components.

(b) A [blood centre] Technician with the



qualification and experience as specified in Part XII B of Schedule F or an experienced laboratory technician trained in blood grouping and cross matching.

refrigerator of appropriate capacity fitted with alarm device and temperature indicator with regular temperature monitoring shall be provided to store blood units between 2°C to 8°C and if the components are proposed to be stored specialised equipments as specified in Part XII B of Schedule F shall also be provided.

(7) The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall maintain records and registers including details of procurement of Whole Human Blood I.P. and/or blood components, as required under Part XII B of Schedule F.

(8) The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall store samples of donors blood as well as patients sera for a period of seven days after transfusion.]

[6.***]

7. Quinine Sulphate

The provisions of sub-section (a) (i) of Section 18 of the Act to the following extent-

- (i) the colour of the drug may be pink, owing to its being coloured with an edible pink colouring matter;
- (ii) the B.P. tests for readily carbonisable substances produce a yellow colour of an intensity about four times the colour produced with quinine sulphate conforming to the B.P. standard;
- (iii) other Cinchona alkaloids present shall not exceed six per cent; and
- (iv) the residue on incineration shall not exceed 0.14 per cent.

[8.***]

9. Magnesium Sulphate.

The provisions of sub-clause (i) of clause (a) of Section 18 of the Act to the following extent:- Chlorides present in the salt shall not exceed 0.12 per cent in the case of the produce prepared from sea water.]

10. The following substances which are used both as articles of food as well as drugs: All provisions of Chapter IV of the Act and the Rules thereunder

(i) all condensed or powdered milk whether pure, skimmed or malted, fortified with vitamins and minerals or otherwise.

(ii) Farex, Oats, ⁴[***] and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use.

(iii) Virol, Bovril, Chicken essence and all other similar predigested foods.

⁵[(iv) Ginger, Pepper, Cumin, Cinnamon and all other similar spices and condiments unless they are specially labelled as conforming to the standards in the Indian Pharmacopoeia or the Official Pharmacopoeias and official compendia of drug standards prescribed under the Act and rules made thereunder.]]

[11. * * *]

⁷[12. Substances intended to be used for destruction of vermin or insects which cause disease in human beings or animals, *vis.* Insecticides and Disinfectants. The provision of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence ²³subject to the condition that provision of condition (17) of Rule 65 of the Drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling such substances.]

[13. The following household remedies, namely:— The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered with a sale licence in Form 20A subject to the following conditions:—

²[(1) Aspirin tablets]

³[(2) Paracetamol Tablets]

(3) Analgesic Balms.

(4) Antacid preparations.

(5) Gripe Water for use of infants.

(6) Inhalers, containing drugs for treatment of cold and nasal congestion.

(7) Syrups, lozenges, pills and tablets for cough.

(8) Liniments for external use.

(9) Skin ointments and ointments for bums.

(10) Absorbent cotton wool, bandages absorbent gauze and adhesive plaster.

(11) Castor Oil, Liquid Paraffin and Epsom salt.

(12) Eucalyptus Oil.

(13) Tincture Iodine, Tincture Benzoin Co. and

(a) The drugs are sold only in a village having population of not more than one thousand persons and where there is no licensed dealer under the Drugs and Cosmetics Act.

(b) The drugs do not contain any substance specified in 4[Schedules G, H or X.]

(c) The drugs are sold in the original unopened containers of the licensed

Mercurochrome in containers not exceeding manufacturers.
100 ml.

- (14) Tablets of Quinine Sulphate I.P. (d) When the drugs are sold under clause (a)
(15) Tablets of Iodochlorohydroxy quinoline— condition 3 under "Conditions of licence" of
250 mg.] Form 20-B shall not apply.

⁵[14. Mechanical Contraceptives

The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered by a sale licence 6[subject to the condition that the provisions of condition (17) of Rule 65 of the Drugs Rules, 1945, are complied with by the person stocking or selling mechanical contraceptives.]

- 1[14A. Vaginal contraceptive pessaries containing Nonoxynol. The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by a sale licence subject to the condition that the provisions of clause (17) of rule 65 of the Drugs Rules, 1945 are complied with by the person stocking or selling this contraceptive.]

- 2[15. Chemical contraceptive having the following composition per tablet: The provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered by a sale licence.]

- (1) DL-Norgestrel — 0.30 mg. Ethinyloestradiol — 0.30 mg.
(2) Levonorgestrel — 0.15 mg. Ethinyloestradiol — 0.03 mg.
(3) Centchroman — 30 mg.
(4) Desogestrel — 0.150 mg. Ethinyloestradiol - 0.030 mg.
(5) Levonorgestrel — 0.1 mg. Ethinyloestradiol — 0.02 mg.]

33[16. ***]

- 5[17. Ophthalmic ointments of the Tetracycline group of drugs. Persons authorised by the Government to distribute or sell the drugs under the National Trachoma Control Programme shall be exempted from the provisions of Chapter IV of the Act and the rules made thereunder, which require the drugs to be covered by a sale licence.]

35[18.* * *]

- 7[19. Hair Fixers, namely mucilagenous preparations containing gums, used by men for fixing beard. The provisions of Chapter IV of the Act and the rules thereunder.]

- 1 [20. Radio Pharmaceuticals. All the provisions of Chapter IV of the Act and the Rules made thereunder.]

2[21. Tablets of Chloroquine Salts.

The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered by a sale licence, provided the drug in strip pack is sold under the Commercial Distribution Scheme of the National Malaria Eradication Programme and duly labelled as "National Malaria Eradication Programme—Ministry of Health and Family Welfare Government of India."]

3[22. Sales from restaurant cars of trains and from coastal ships of household remedies, which do not require the supervision of a qualified person for their sale.

The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence, subject to the following conditions namely:—

(a) The records of purchase and sale of drugs shall be maintained by the person-in-charge of sale of such drugs, which shall be available for inspection by an Inspector appointed under the Act;

(b) the place where such drugs are stocked shall be open to inspection by an Inspector appointed under the Act who can, if necessary, take samples for test.]

4[23. Drugs supplied by (i) Multipurpose Workers attached to Primary Health Centres/Sub-Centres, (ii) Community Health Volunteers under the Rural Health Scheme, (iii) Nurses, Auxiliary Nurses, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres, Primary Health Centres/Sub-Centres, (iv) Anganwadi Workers; and (v) Community Health Officers at Ayushman Bharat Health and Wellness Centres.]

The provisions of Chapter IV of the Act and the rules thereunder, which require them to be covered by a sale licence, provided the drugs are supplied under the Health or Family Welfare Programme of the Central or State Government.]

1 [24. Homoeopathic medicines supplied by a registered Homoeopathic medical practitioner to his own patient or Homoeopathic medicines supplied by a registered Homoeopathic medical practitioner at the request of another such practitioner provided the registered Homoeopathic medical practitioner is not

All the provisions of Chapter IV of the Act and rules made thereunder subject to the following conditions:—

(1) The Homoeopathic medicines shall be purchased only from a dealer or a manufacturer licensed under the Drugs and Cosmetics Rules, 1945.

(2) The premises where the Homoeopathic medicines are stocked shall be open to inspection by an Inspector appointed under the Act, who may, if necessary, take samples for test.]

(a) keeping an open shop, or (b) selling across the counter or, (c) engaged in the importation, manufacture, distribution or sale of Homoeopathic medicines in India to a degree which renders him liable to the provisions of Chapter IV of the Act and the Rules made thereunder.

2[25. Preparations applied to human body for the purpose of repelling insects like mosquitoes.] The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence subject to the conditions that such a product has been manufactured under a valid drug manufacturing licence.

3[26. Medicated Dressings and Bandages for First Aid.] The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence, subject to the conditions that such a product has been manufactured under a valid drug manufacturing licence.]

4[27. 5[Oral Rehydration Salts (Manufactured as per the following formula):-Composition of the formulation in terms of the amount in g, to be dissolved in sufficient water to produce 1000 ml.] The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence, subject to the conditions that such a product has been manufactured under a valid drug manufacturing Licence.]

- Sodium Chloride 2.6
- Dextrose (anhydrous) or 13.5
- Dextrose mono-hydrate 14.85
- Potassium chloride 1.5
- Sodium Citrate 2.9]

[28. White or Yellow Petroleum Jelly I.P. (Non-perfumed)] The Provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by a sale licence subject to the conditions that such a product has been manufactured under a valid drug manufacturing licence.]

2[29. Morphine Tablets

The Provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by a sale licence, subject to the following conditions, namely:—

(i) The drug shall be supplied by the Palliative Care Centres approved by the State Government to terminally ill cancer patients.

(ii) The drug shall be kept under the custody of the Medical Officer-in-charge of the said Centre.

(iii) The drug shall be purchased from a dealer or a manufacturer who holds licence under these rules, and records of such purchases showing the names and quantities together with their batch

numbers, and names and addresses of the manufacturers or dealers and the names and addresses of the patients to whom supplies have been made shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may also take samples for test.

30. Whole Human Blood collected and transfused by Centres run by Armed Forces Medical Services in border areas, small mid-zonal hospitals including peripheral hospitals, Field Ambulances, Mobile medical units including blood supply units in border, sensitive and field areas. All the provisions of Chapter IV of the Act and rules made thereunder which require them to be covered by a licence to operate a 311[Blood Centre] for collection, storage and processing of whole human blood for sale or distribution subject to the following conditions:—

(i) These Centres shall collect, process and transfuse blood in emergent situations which require life saving emergency surgeries/or transfusion.

(ii) The Centres shall be under the active direction and personal supervision of a qualified Medical Officer, possessing the qualifications and experiences specified in condition (i) of rule 122G.

(iii) Each blood unit shall be tested before use for freedom from HIV I and II antibodies, Hepatitis B surface antigen, malarial parasites and other tests specified under the monograph "Whole Human Blood" in current edition of Indian Pharmacopoeia.

(iv) These Centres shall have adequate infrastructure facilities for storage and transportation of blood.

(v) The blood collected and tested by such Centres shall be transfused by the Centre itself and may be made available for use of other peripheral Armed Forces hospitals or centres during operational circumstances.]

1 [31. Homoeopathic Medicines

The provisions of Chapter IV of the Act and the rules made thereunder which relates to sale licence in Form 20C, subject to the following

conditions:—

(i) These medicines shall be sold in the original sealed small quantity packings of the licensed manufacturers;

(ii) Medicines shall be stocked and sold by retail dealers of medicines licensed under rule 61;

(iii) Medicines shall be stored separately from other allopathic drugs;

(iv) Medicines shall be purchased from a manufacturer or a dealer licensed under these rules; and

(v) Purchase and sale records of medicines shall be maintained by the dealer for a minimum period of three years.]

1[32. First Aid kit supplied along with motor vehicle by the manufacturer or its distributor at the time of first sale of vehicle.

The provisions of Chapter IV of the Act and rules made thereunder which require them to be covered by a sale licence, subject to the condition that the drug items are procured from a manufacturer or a dealer licensed under the rules.]

2[33. Nicotine gum [and Lozenges] containing upto 2 mg. of nicotine

The provisions of Chapter IV of the Act and the Rules made thereunder which require them to be covered by a sale licence subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.]

4[34. Production of Oxygen 93 per cent. USP or Oxygen 93 per cent. IP, produced from air by the molecular sieve process or Oxygen 93 per cent, be supplied from liquid Oxygen, by a hospital or medical institute for their captive consumption.

The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by manufacturing licence under the rules, provided that the production facilities shall be open to inspections by an Inspector appointed under the Act, who can, if necessary, take samples for test.]

5[35. Homeopathic hair oils having active ingredients up to 3X potency only.

The provisions of Chapter IV of the Act and the rules made thereunder which require them to be regulated with a sale license subject to the

condition that such products have been manufactured under a valid manufacturing license and sold in the original sealed packing of the licensed manufacturers.

36. Custom made devices.

All provisions of Chapter IV of the Act and the rules made thereunder, subject to the condition that the device being specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design, characteristics and the same is intended for the sole use of a particular patient and the label contain the words 'custom made device'.

Explanation.—Mass produced devices, which only need adoption to meet the specific requirement of a medical practitioner or any other professional user, shall not be considered as custom made device.

37. Zinc sulphate tablets and oral solutions having 10 mg and 20 mg of elemental zinc.

The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence, subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.]

1[38. Sterile solutions intended for parenteral administration with 100 ml in one container of the finished dosage form for single use manufactured for export only.

The provisions of Chapter IV of the Act and rules made thereunder which require them to obtain a licence in Form 28D or 28DA from the Central Licence Approving Authority subject to the condition that such drugs have been manufactured for export purpose only under a licence granted by the State Licensing Authority.]

³[SCHEDULE L-I

(See rules 74, 78 and 150E)

GOOD LABORATORY PRACTICES AND REQUIREMENT OF PREMISES AND EQUIPMENTS

1. General Requirements: