41. Parkinsonism
42. Piles and Fistulae
43. Power to rejuvenate
44. Premature ageing
45. Premature greying of hair
46. Rheumatic Heart Diseases
47. Sexual Impotence, Premature ejaculation and spermatorrhoea
48. Spondylitis
49. Stammering
50. Stones in gall-bladder, kidney, bladder
51. Varicose Vein.

SCHEDULE K
(See rule 123)

Class of Drugs
1. Drugs falling under clause (b) (i) of Section 3 of the Drugs and Cosmetics Act, not intended for medicinal use.

Extent and Conditions of Exemption
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.”

1[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 requirement to take out licences for retail sale under clause (c) of Section 18 of the Act.]

4[3.* * *]

5[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 rules thereunder.

All the provisions of Chapter IV of the Act and the Rules made thereunder, subject to the following conditions:

1[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 samples for test.]

2. In the case of medicine containing a substance specified in 5[Schedule G, H or X] of 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 "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 & 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.

8[3. The drug will be stored under proper storage conditions as directed on the label.]

9[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.]

10[5A. Drugs supplied by a hospital or dispensary maintained or supported by Government or local body.]

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) 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) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its 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) The captive consumption of Whole Human Blood IP or its components in the First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall not be more than 2000 units annually.

(3) The Whole Human Blood and / or its components shall be procured only from Government Blood Bank 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 and / or any 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 bank 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.
(6) The First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall have an area of 10 sq. metres. It shall be well lighted, clean and preferably air- conditioned. Blood bank 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, specialized equipment’s 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 / or any Hospital shall maintain records and registers including details of procurements of Whole Human Blood IP and / or blood components, as required under Part XII B Schedule F.

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

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. 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 -

(i) all condensed or powdered milk whether

All provisions of Chapter IV of the Act and the Rules thereunder
pure, skimmed or malted, fortified with vitamins and minerals or otherwise.

(ii) Farex, Oats, 19[***] 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.

(iv) 20[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 Pharmacopoeia and official compendia of drug standards prescribed under the Act and Rules made thereunder.]

21[11.* * *]

22[12. Substances intended to be used for destruction of vermin or insects which cause disease in human beings or animals, viz. Insecticides and Disinfectants.]

23[13. The following household remedies, namely-

(1) 25[Aspirin tablets.]

(2) 25[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 burns.

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

(11) Castor Oil, liquid Paraffin and Epsom Salt.

(12) Eucalyptus Oil

(13) Tincture Iodine, Tincture Benzoic O. and Mercurochrome in containers not exceeding 100 ml.

(14) Tablets of Quinine Sulphate I.P.

(15) Tablets of Iodochlorohydroxy quinoline-250 mg.]

24[14. Mechanical Contraceptives

The provision of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence 23[subject 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.]

The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered with a sales licence in Form 20-A subject to the following conditions—

(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 27[Schedules G, H or X];

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

(d) When the drugs are sold under clause (a) condition 3 under “Conditions of licence” of Form 20-B shall not apply.
14A. Vaginal contraceptive pessaries containing Nonoxynol.

15. Chemical contraceptive having the following composition per tablet:
   (1) DL-Norgestrel-0.30 mg.
       Ethinyloestradiol-0.03 mg.
   (2) Levonorgestrel-0.15 mg.
       Ethinyloestradiol-0.03 mg.
   (3) Centchroman-30mg.
   (4) Desogestrel -0.150mg.
       Ethinyloestradiol 0.030mg.
   (5) Levonorgestrel 0.1mg.
       Ethinyloestradiol 0.02mg

16. Cosmetics

17. Ophthalmic ointments of the Tetracycline group of drugs

18. * * *

19. Hair Fixers, namely mucilaginous preparations containing gums, used by men for fixing beard.

20. Radio Pharmaceuticals.

21. Tablets of Chloroquine Salts.

covered by a sale licence subject to the condition that the provisions of condition (17) of Rule 65 of the Drugs and Cosmetics Rules, 1945, are complied with by the person stocking or selling mechanical contraceptives.}

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 and Cosmetics Rules, 1945 are complied with by the person stocking or selling this contraceptive.

The provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered by a sale licence.

The provisions of Chapter IV of the Act and the Rules made thereunder, which require them to be covered by a licence for sale provided that the cosmetics sold, if of Indian origin, are manufactured by licensed manufacturers.

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.

The provisions of Chapter IV of the Act and the rules thereunder.

All the provisions of Chapter IV of the Act and the rules made thereunder.

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...
39[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 the 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, takes samples for test.]

40[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 and (iv) Anganwadi Workers.

All The provisions of Chapter IV of the Act and 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.]

42[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 (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

(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.”]

44[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.

44[26. Medicated Dressing 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.]
27. Oral Rehydration Salts (Manufactured as per the following formula):
   - Sodium chloride 3.5 g/litre.
   - Trisodium citrate dehydrate 2.9 g/litre
   - Potassium Chloride 1.5 g/litre.
   May be replaced by Sodium bicarbonate (Sodium hydrogen Carbonate) 2.5 g/litre, when citrate salt is not available.


29. Morphine Tablets

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 and other field medical units including blood supply units in border, sensitive and field areas.

The provisions of Chapter IV of the Act and Rules thereunder which required 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.

The provisions of Chapter IV of the Act and Rules thereunder which required 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.

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.

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 Blood Bank 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 lifesaving emergency surgeries/or transfusion.

(ii) These Centres shall be under the active direction and personal supervision of a qualified Medical Officer, possessing the
(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.

31. The following Homoeopathic Medicines, namely:

(a) ***

(b) Homoeopathic Ointments, each in 25gm. Tube:
   (i) Arnica Montana
   (ii) Calendula Officinalis
   (iii) Cantharis
   (iv) Rhus Toxicodendron

(c) Biochemic tissue remedies in tablet forms, in generic names only, each in 20gm. Packing in 3X and 6X trituration-
   (i) Calcarea Phosphorica
   (ii) Calcarea Sulphurica
   (iii) Ferrum Phosphoricum
   (iv) Kali Muriaticum
   (v) Kali Phosphoricum
   (vi) Kali Sulphuricum
   (vii) Magnesium Phosphoricum
   (viii) Magnesia Sulphurica
   (ix) Natrum Muriaticum
   (x) Natrum Phosphoricum
   (xi) Natrum Sulphuricum
   (xii) Silica

(d) Homoeopathic medicines, mentioned below, in pills, each in 30C potency, in sealed original packing of manufacturer of 8 gms:
   (i) Arnica Montana
   (ii) Aconitum Napellus
   (iii) Arsenicum Album

The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered with a sale licence in Form 20-C, subject to the following conditions:

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

(ii) These medicines may be stocked and sold by retail of medicines licensed under rule 61.

(iii) These medicines shall be stored separately from other allopathic drugs.

(iv) These medicines shall be purchased from a manufacturer or a dealer licensed under these rules.

(v) The purchase and sale records of these medicines shall be maintained by the dealer for minimum period of three years.

(vi) These medicines shall be labelled in generic / pharmacopoeial names only.
(iv) Aloe Socotrina
(v) Apis Mellifica
(vi) Allium Cepa
(vii) Bryonia Alba
(viii) Borax
(ix) Belladonna
(x) Cantharis
(xi) Carbo Vegetabilis
(xii) Cina
(xiii) Colocythis
(xiv) Calendula Officinalis
(xv) Caulophyllum Thalictroides
(xvi) Cocculus Indicus
(xvii) Chamomilla
(xviii) Drosera Rotundifolia
(xix) Hypeicum Perforatum
(xx) Hepar Sulphur
(xxi) Ipecacuanha
(xxii) Ledum Palustre
(xxiii) Millefolium
(xxiv) Mercurius Solubilis
(xxv) Nux Vomica
(xxvi) Pulsatilla Nigricans
(xxvii) Podophyllum Peltatum
(xxviii) Plantago Major
(xxix) Rhus Toxicodendron
(XXX) Ruta Graveolens
(XXXI) Symphytum Officinalis
(XXXII) Veratrum Album

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

33. Nicotine gum and Lozenges containing up to 2 mg of nicotine

34. Production of Oxygen 93 per cent USP, produced from air by the molecular sieve process, by a hospital or Medical Institute for their captive consumption.
50. Homoeopathic 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 covered with a sale licence [57[***] subject to the condition that such a product has been manufactured under a valid manufacturing licence and sold in the original sealed packing of the licensed manufacturers.

58. 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 is intended for the sole use of a particular patient and the label should bear the word “custom made device.”

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

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4. Item 3 and 4 omitted by Notification No. F.1-6/62-D dt. 2-7-1969.
17. Added by notification No. F.1-19/50-D.S, dt: 30.3.1953.
57. The words “in Form 20C” omitted by G.S.R. 107 (E), dt: 17.2.2015.