

SCHEDULE K

[See rule 123]

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemption</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".
¹ * * *	* * * * *
² [2A] Quinine and other antimalarial drugs.	Persons selling the drug 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) ³ of Section 18 of the Act.
⁴ * * *	* * * * *
⁴ * * *	* * * * *
³ [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	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 the 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.

1. Omitted by Government of India Notification No. F.1-56/47-D, dt. 16.1.1950).

2. Added by Notification No. F. I-2/47-D dt. 13-2-1950.

3. Amended by Notification No. F. I-22/59-D dt. 9-4-1960.

4. Omitted by Notification No. F.I-6/62-D dt. 2-7-69.

5. Amended by Min. of Health & F.W. Notification No. X- 11013/3/76-D & MS, dt. 19-8-1978.

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemptions</i>
<p>drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules thereunder.</p>	<p>(2) In the case of medicine containing a substance specified in ¹[Schedule G, H or X] the following additional conditions shall be complied with]:</p> <p>(a) the medicine shall be labelled with the name and address of the registered medical practitioner by whom it is supplied;</p> <p>(b) if the medicine is for external application, it shall be labelled with the words ²* * * “For external use only” or if it is for internal use with the dose;</p> <p>(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;</p> <p>(d) the entry in the register shall be given a number and that number shall be entered on the label of the container;</p> <p>(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.</p> <p>³[(3)The drug will be stored under proper storage conditions as directed on the label.]</p>
<p>5A. Drugs supplied by a hospital or dispensary maintained or supported by Government or local body ⁴* * *</p>	<p>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 :</p>

1. Subs. by G.S.R. 462(E), dt. 22.6.1982.

2. Omitted G.S.R. 462(E), dt. 22.6.1982.

3. Ins. G.S.R. 460(E), dt. 22.6.1984.

4. Omitted G.S.R. 812(E), dt. 14.11.1994.

*Class of Drugs**Extent and Conditions of Exemptions*

(1) the dispensing and supply of drugs shall be carried out by or under the supervision of a ¹[registered pharmacist];

(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 the proper storage conditions.

²[(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.]

³[5B. Whole Human Blood I.P. and/or its components stored for transfusion by a First Referral Unit Community Health Centre, Primary Health Centre and 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 I.P. 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 Healthy Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval.

1. Subs. by G.S.R. 676(E), dt. 6.9.1994.
 2. Ins. by G.S.R. 648(E), dated 16.9.2002 (w.e.f. 1.10.2002).
 3. Ins. by G.S.R. 909(E), dated 20.12.2001.

*Class of Drugs**Extent and Conditions of Exemptions*

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 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 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 procurements 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.]

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Class of Drugs	Extent and Conditions of Exemptions
7. Quinine Sulphate	<p>The provision of sub-section (a)(i) of section 18 of the Act to the following extent:¹</p> <p>(i) the colour of the drug may be pink, owing to its being coloured with an edible pink colouring matter;</p>
1. Item 6 omitted by G.S.R. 681(E), dated 5.12.1980.	
¹ [9. Magnesium Sulphate	<p>(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;</p> <p>(iii) other Cinchona alkaloids present shall not exceed six per cent; and</p> <p>(iv) the residue on incineration shall not exceed 0.14 per cent.</p> <p>The provisions of sub-clause (i) of clause (ii) of section 18 of the Act to the following extent: –</p> <p>Chlorides present in the salt shall not exceed 0.12 per cent in the case of, the produce prepared from sea water.]</p>
² [10. The following substances which are used both as articles of food as well as drugs:–	All the provisions of Chapter IV of the Act and the Rules thereunder.
	<p>(i) all condensed or powdered milk whether pure skimmed or malted, fortified with vitamins and minerals or otherwise</p> <p>(ii) Farex, Oats and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use.</p> <p>(iii) Virol, Bovril, Chicken essence and all other similar predigested foods.</p> <p>¹(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</p>

*Class of Drugs**Extent and Conditions of Exemptions*

official compendia of drug standards prescribed under the Act and rules made thereunder.

- ³12. Substances intended to be used for destruction of vermin or insects, which The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered

1.. Added by Notification No.F.I-19/50-DS , dated 30.3.1953

2. .Added by. Notification No. DR/Sch. Ddk/F. I-40/54-DS , dated 27.1.1955.

3. Amended by Notification F. 1-20/60-D, dt.24.1.1964.

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13. ²[The following household remedies, namely:-

- ³[(1) Asprin Tablets.]
⁴[(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 burns.
(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 Mercurochrome solution in containers not exceeding 100 ml.
(14) Tablets of Quinine Sulphate I.P.
(15) Tablets of Iodochlorohydroxy quinoline – 250 mg.]

The provision of Chapter IV of the Act and the Rules thereunder which require them to be covered with a sale 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 licenced dealer under the Drugs and Cosmetics Act;

(b) the drugs do not contain any substance specified in ⁵[Schedule 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.

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemptions</i>
⁶ 14. Mechanical Contraceptives	<p>The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered by a sale licence, ⁷[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.]</p>
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¹ [14 7. Subs. by G.S.R. 926, dated 16.7.1977. containing a reference to:-	<p>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.]</p>
² [15. Chemical contraceptive having the following composition per tablet:- ² [(1) DL-Norgestrel – 0.3 mg. Ethinyloestradiol – 0.03 mg. (2) Levonorgestrel – 0.15 mg. Ethinylestradiol – 0.3 mg. (3) Centchroman – 30 mg. ³ [(4) Desogestrel -- 0.150 mg. Ethinyloestradiol – 0.030 mg. (5) Levonorgestrel -- 0.1 mg. Ethinyloestradiol -0.02 mg.]	<p>The provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered with a sale licence.]</p>
⁴ [16 Cosmetics.	<p>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.]</p>
⁵ [17. Ophthalmic ointments of the Tetracycline group of drugs.	<p>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.</p>
⁶ * * * *	<p>* * * *</p>
⁷ [19 Hair Fixers, namely mucilagenous preparations containing gums, used by men for fixing beard.	<p>The provisions of Chapter IV of the Act and the rules thereunder.]</p>

Class of Drugs

Extent and Conditions of Exemptions

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1. Ins. by G.S.R. 784(E), dt. 28.8.1989.
 2. Subs. by G.S.R. 730 (E), dt. 10.12.1991 and corrected by G.S.R. 305(E), dt. 4.3.1992.
 3. Ins. by G.S.R. 648(E), dt. 16.9.2002.
 4. Ins. by Notification No. 1-36/64-D, dt. 17.8.1964.
 5. Ins. by . Notification No. I-21/63-D, dt. 4.1.1965.
 6. Omitted by Notification No. G.S.R. 1594, dt. 13.11.1976.]
 7. Ins. by Notification No. S.O.2139, dt. 12.8.1971.

- ¹[20 Radio Pharmaceuticals. All the provisions of Chapter IV of the Act and the rules made hereunder.]
- ²[21 Tablets of Chloroquine Salts. The provisions of Chapter IV of the Act and the 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 registered pharmacist for their sale. The provisions of Chapter IV of the Act and the rules thereunder which require them to be covered with 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 ⁵*** (iii) Nurses, Auxiliary Nurse, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres/Primary Health Centres/Sub-Centres and ⁶[(iv) Anganwadi Workers.]
- 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.]

Class of Drugs

Extent and Conditions of Exemptions

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1. Ins. by. G.S.R. 926 , dt. 16.7.1977.
 2. Ins. by. G.S.R. 697(E) , dt. 11.11.1977.
 3. Ins. by G.S.R. 1241(E) , dt. 15.9.1979.
 4. Ins. by. G.S.R. 540(E) , dt. 22.9.1980
 5. Omitted by. G.S.R. 784 (E) , dt. 28.8.1989
 6. Added by G.S.R. 784, dt. 28.8.1989.

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| <p>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 (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.</p> | <p>All the provisions of Chapter IV of the Act and the rules made thereunder subject to the following conditions:-</p> <p>(1) The Homoeopathic medicines shall be purchased only from a dealer or a manufacturer licensed under the Drugs and Cosmetics Rules 1945.</p> <p>(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".]</p> |
| <p>²[25. Preparations applied to human body for the purpose repelling insects like mosquitoes.</p> | <p>The provisions of Chapter IV of the Act and Rules thereunder which require them to be covered by a sale licence subject to conditions that such a product has been manufactured under a valid drug manufacturing licence.</p> |
| <p>26. ³[Medicated Dressings and Bandages for First Aid.]</p> | <p>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.]</p> |
| <p>⁴[27 Oral Rehydration Salts (Manufactured as per the following formula) :
Sodium chloride 3.5 g/litre.
* Trisodium citrate dihydrate 2.9 g/litre.
Potassium Chloride 1.5 g/litre</p> <p><i>*May be replaced by Sodium bicarbonate (Sodium hydrogen Carbonate) 2.5 g/litre,</i></p> | <p>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.]</p> |

*Class of Drugs**Extent and Conditions of Exemptions*

when citrate salt is not available.

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1. Ins. by G.S.R. 680(E), dt. 5.12.1980.
 2. Ins. by G.S.R. 1060(E), dt. 5.9.1986.
 3. Subs. by G.S.R. 371(E), dt. 24.3.1988.
 4. Ins. by G.S.R. 677(E), dt. 2.6.1988.

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| ¹ [28 White or Yellow Petroleum Jelly I.P. (Non-perfumed). | <p>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.]</p> |
| ² [29 Morphine Tablets | <p>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:-</p> <p>(i) The drug shall be supplied by the Palliative Care Centres approved by the State Government to terminally-ill cancer patients.</p> <p>(ii) The drug shall be kept under the custody of the Medical Officer in-charge of the said centre.</p> <p>(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.</p> |
| 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. | <p>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-</p> <p>(i) These Centres shall collect, process and transfuse blood in emergent situations which require life saving emergency surgeries/or transfusion.</p> <p>(ii) These Centres shall be under the active direction and personal supervision of a qualified</p> |

*Class of Drugs**Extent and Conditions of Exemptions*

Medical Officer, possessing the qualifications and experiences specified in condition (i) of rule 122-G.

(iii) Each blood unit shall be tested before 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.

1. Ins. by G.S.R. 753(E), dt. 4.11.1999.

2. Ins. by G.S.R. 6(E), dt. 4.1.2001

(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 centers during operational circumstances.]

¹[31. The following Homoeopathic Medicines, namely:-
(a) Arnica Montana Hair Oil

- (b) Homeopathic ointments, each in 15 gm. Tube:
(i) Arnica Montana
(ii) Calendula Officinalis
(iii) Cantharis
(iv) Rhus Toxicodendron

(c) Biochemic tissue remedies in tablets forms, in generic names only, each in 20 gm. Packing in 3x and 6x trituration :

- (i) Calcarea Phosphorica
(ii) Calcarea Sulphurica
(iii) Ferum Phosphoricum
(iv) Kali Muriaticum
(v) Kali Phosphoricum

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 dealers 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.

*Class of Drugs**Extent and Conditions of Exemptions*

1 Ins. by . Notification No. G.S.R. 218(E) , dt. 28.3.2001.

(vi) Kali Sulphuricum
(vii) Magnesium
Phosphoricum

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

(vi) These medicines shall be labelled in generic/pharmacopoeial names only.]

(viii) Megnesia Sulphurica
(ix) Natrum Muriaticum
(x) Natrum Phosphoricum
(xi) Natrum Sulphuricum
(xii) Silicea

(d) Homoeopathic medicines, mentioned below, in pills, each in 30 C potency, in sealed original packing of manufacturer of 8 gms:—

(i) Arnica Montana
(ii) Aconitum Napellus
(iii) Arsenicum Album
(iv) Aloe Socotrina
(v) Apis Mellifica
(vi) Allium Cepa
(vii) Bryonia alba
(viii) Borax
(ix) Belladonna
(x) Cantharis
(xi) Carbo Vegetabilis
(xii) Cina
(xiii) Colocynthis
(xiv) Calendula Officinalis
(xv) Caulophyllum Thalictroides
(xvi) Cocculus Indicus
(xvii) Drosera Rotundifolia
(xix) Hypericum Perforatum
(xx) Hepar Sulphur
(xxi) Ipecacuanha
(xxii) Ledum Palustre
(xxiii) Millefolium
(xxiv) Mercurius Solubillis
(xxv) Nux Vomica
(xxvi) Pulsatilla Nigricans
(xxvii) Podophyllum Peltatum

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemptions</i>
(xxviii) Plantago Major (xxix) Rhus Toxicodendron (xxx) Ruta Graveolens (xxxi) Symphytum Officinale (xxxii) Veratrum Album	

² [33. Nicotine gum containing up to 2 mg. of nicotine.	<p>Motor vehicle by the manufacturer or its distributor at the time of first sale of vehicle.</p> <p>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 dealer licensed under the rules.]</p> <p>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.]</p>
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1 Ins. by G.S.R. 648 (E) , dt. 16.9.2002.

2 Ins. by G.S.R. 549(E), dt. 16.6.2005.