

***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

2. Ergot and preparations containing Ergot not in a form to be administered parenterally.

3. Adrenaline and preparations containing Adrenaline not in a form to be administered parenterally.

4. Fish Liver Oil and preparations containing Fish Liver Oil.

5. Vitamins and preparations containing any vitamins not in a form to be administered parenterally.

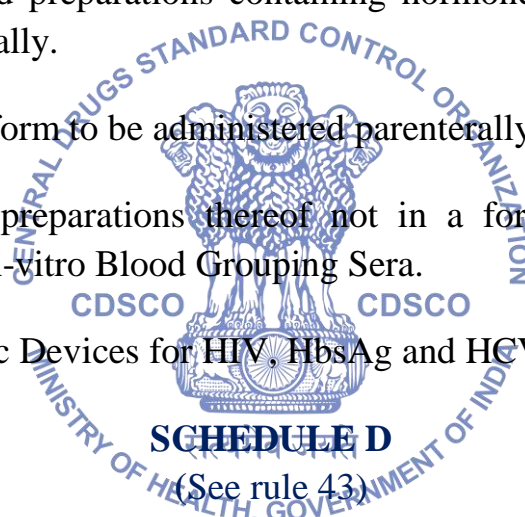
6. Liver extract and preparations containing liver extract not in a form to be administered parenterally.

7. Hormones and preparations containing hormones not in a form to be administered parenterally.

8. Vaccine not in a form to be administered parenterally.

⁵[9. Antibiotics and preparations thereof not in a form to be administered parenterally.] ⁶[10. In-vitro Blood Grouping Sera.

11. In-vitro Diagnostic Devices for HIV, HbsAg and HCV.]



SCHEDULE D

(See rule 43)

Class of drugs

1. ³⁰²[Substances not intended for medicinal use excluding those intended to be used as drugs after further purification or rendering them sterile.]

Extent and conditions of exemption

All provisions of Chapter III of the Act and Rules thereunder subject to the condition that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medical uses, and if imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use or

is of commercial quality. [Further, permission from licensing authority as defined in clause (b) of rule 21 has to be obtained for import of the substance for non-medicinal use without registration and import licence.]

⁴[5. The following substances, which are used both as articles of food as well as drugs:—

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

(ii) Farex, Oats, Lactose 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 food.

(iv) Ginger, Pepper, Cumin, Cinnamon and all other similar spices and condiments unless they are specifically labelled as conforming to the standards in the ⁵[Indian Pharmacopoeia or

the official pharmacopoeias and the official compendia of drug standards prescribed under the Act and Rules made thereunder.]]

⁶[6. Drugs and cosmetics imported for

All the provisions of Chapter III of the Act and Rules thereunder.

The provisions of Chapter III of the Act and rules thereunder which require them to be covered by an import licence, import registration and import through notified port of entry, subject to the conditions that these drugs and ⁷[***] shall not be diverted for sale in the country: Provided that such imported drugs and cosmetics may be permitted to the domestic area if they meet the requirements of standard procedure for import and registration as required under Chapter III of the Act and rules thereunder.]

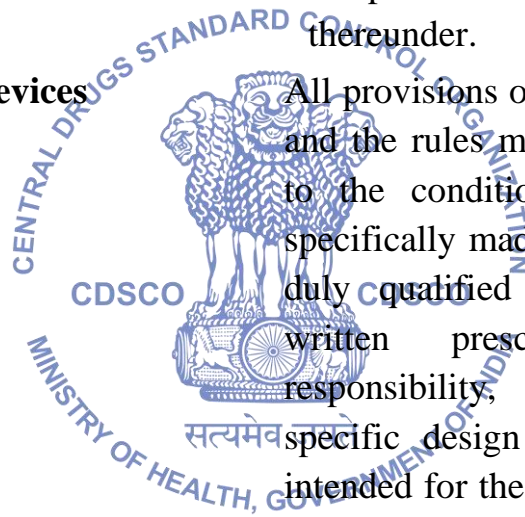
The provisions of Chapter III of the Act and rules thereunder which

manufacture and export by units situated in "Special Economic Zones" as notified by the Government of India from time to time.

required them to be covered by an import licence, import registration and import through notified port of entry, subject to the conditions that these drugs and cosmetics shall not be diverted for sale in the country:

Provided that such imported drugs and cosmetics may be permitted to the domestic area if they meet the requirements of standard procedure for import and registration as required under Chapter III of the Act and rules thereunder.

'7. Custom Made Devices



All provisions of Chapter III of the Act and the rules made thereunder, subject to the condition that the device is 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.]

[283](#) Delete, whichever is not applicable.

[284](#) Added by Notification No. F. 1-14/68-D (G.S.R. 3869), dated 26th October, 1968 (w.e.f. 2-11-1968).

[285](#) Subs, by G.S.R. 592(E), dated 13th August, 2008 (w.e.f. 13-8-2008).

[286](#) Ins. by G.S.R. 223(E), dated 18th March, 2019 (w.e.f. 19-3-2019).

[287](#) The words "or renewal" omitted by G.S.R. 1337(E), dated 27th October, 2017 (w.e.f. 27-10-2017).

[288](#) The words "items of cosmetics" omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020).

[289](#) The word "Cosmetics" omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020).

[290](#) Ins. by G.S.R. 223(E), dated 18th March, 2019 (w.e.f. 19-3-2019).

[291](#) The word "items of cosmetics" omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020).

[292](#) Subs, by G.S.R. 231(E), dated 4th June, 1996 (w.e.f. 4-6-1996).

[293](#) The words "and any certificate of renewal in Form 38" omitted by G.S.R. 499(E), dated 17th July, 2019 (w.e.f. 17-7-2019).

[294](#) The words "or items of cosmetics" omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020).

[295](#) FORM 38 omitted by G.S.R. 1337(E), dated 27th October, 2017 (w.e.f. 27-10-2017). Earlier FORM 38 was inserted by G.S.R. 1172, dated 23rd August, 1977 and amended by G.S.R. 231(E), dated 4th June, 1996 (w.e.f. 4-6-1996).

[296](#) The word "cosmetic" omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020).

[297](#) Subs, by G.S.R. 681(E), dated 6th June 1988 (w.e.f. 6-6-1988).

[298](#) Ins. by G.S.R. 604(E), dated 24th August, 2001 (w.e.f. 1-2-2003).

[299](#) Subs, by G.S.R. 26(E), dated 19th January, 2006 (w.e.f. 19-1-2006).

[300](#) Item "V" relating to "Homeopathic Medicines" and the entries relating thereto omitted by G.S.R. 202(E), dated 22nd March, 2021 (w.e.f. 23-3-2021).

[301](#) Clause (2) omitted by G.S.R. 202(E), dated 22nd March, 2021 (w.e.f. 23-3-2021).

[302](#) Subs, by G.S.R. 360(E), dated 10th April, 2018 for entry under item 1 "Substances not intended for medical use" (w.e.f. 10-4-2018).

[303](#) Subs, by G.S.R. 40(E), dated 29th January, 2001 (w.e.f. 1-6-2001).