



**GOVERNMENT OF INDIA**

**MINISTRY OF HEALTH AND FAMILY  
WELFARE**

**(Department of Health)**

**THE DRUGS AND COSMETICS ACT  
AND RULES**

**THE DRUGS AND COSMETICS ACT, 1940**

**(23 OF 1940)**

**(As amended up to the 31<sup>st</sup> December, 2016)**

**and**

**THE DRUGS AND COSMETICS RULES, 1945**

**(As amended up to the 31<sup>st</sup> December, 2016)**

**SCHEDULE D**

[See Rule 43]

	Class of drugs	Extent and conditions of exemption
1.	Substances not intended for medicinal use	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-medicinal 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 of commercial quality. <sup>1</sup> [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 license.]

<sup>2</sup>[\*\*\*]<sup>3</sup>[\*\*\*]

<sup>4</sup> [5.	The following substances, which are used both as articles of food as well as drugs:-	All provisions of Chapter III of the Act and rules thereunder.
(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 foods.	
(iv)	Ginger, Pepper, Cumin, Cinnamon and all other similar spices and condiments unless they are specifically labelled as conforming to the standards in the <sup>5</sup> [Indian Pharmacopoeia or the official pharmacopoeias and the official compendia of the drug standards prescribed under the Act and rules made thereunder].	

1. Ins. By G.S.R 724 (E), dt:7-11-2013.

2. Serial no 2, 3, omitted by Notfn. No. F-1-6/62-D (S.O.2889), dt: 2-7-1969.

3. Serial no 4, omitted by G.S.R.604 (E) ,dt. 24-8-2001

4. Amended by Notfn. F. 1-53/55-D, dt. 7.1.1957.

5. Amended by G.S.R. 19, dt: 15-12-1977.

Class of drugs	Extent and conditions of exemption
<sup>1</sup> [6. Drugs and cosmetics imported for manufacture and export by units situated in “Special Economic Zones” as notified by the Government of India from time to time.	<p>The provisions of Chapter III of the Act and rules thereunder which 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:</p> <p>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.</p>
<sup>2</sup> [7. Custom Made Devices	<p>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.]</p>

1. Ins. by G.S.R. 528(E), dt. 8.7.2003.  
 2. Ins. By G.S.R 690 (E) dated 25-09-2014.