

**The Gazette of India – Extraordinary**  
**PART II – Section 3 – Sub-Section (ii)**  
**Ministry of Chemicals and Fertilizers**  
**Department of Chemicals and Petrochemicals**  
**New Delhi, dated the 6th January, 1995**

**ORDER**

**S.O. 18 (E).** : In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order, namely:-

**1. Short title and commencement :**

- This Order may be called the Drugs (Prices Control) Order, 1995
- It shall come into force on the date of its publication in the Official Gazette.

**2. Definitions : In this Order, unless the context otherwise requires, –**

- **“bulk drugs”** means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;
- **“capital employed”** means net fixed assets plus working capital of a manufacturer in relation to manufacture of bulk drugs;
- **“ceiling price”** means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph 9;
- **“dealer”** means a person on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business and includes his agent;
- **“distributor”** means a distributor of drugs or his agent or a stockist appointed by a manufacturer or an importer for stocking his drugs for sale to a dealer;
- **“drug”** Includes –
  - all medicines for internal or external use of human beings or animals and all substances intended to be used for, or in the diagnosis treatment, mitigation,

or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

- such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by notification in the official Gazette; and
- bulk drugs and formulations;
- **“Form”** means a form specified in the Second Schedule;
- **“formulation”** means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or and, but shall not include –
  - any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.
  - any medicine included in the Homeopathic system of medicine; and
  - any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply
- **“free reserve”** means a reserve created by appropriation of profits, but does not include reserves provided for contingent disputed claims, goodwill, revaluation and other similar reserves;
- **“Government”** means the Central Government;
- **“import”** with its grammatical variations and cognate expressions means bringing into India from a place outside India, and “importer”, in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer;
- **“manufacture”** in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and “to manufacture” shall be construed accordingly;
- **“manufacturer”** means any person who manufactures a drug;
- **“net-worth”** means the paid-up share capital of a company plus free reserve, if any, and surpluses excluding outside investments which are not readily available for operational activity;
- **“non-Scheduled bulk drug”** means a bulk drug not specified in the First Schedule;

- **“non-Scheduled formulation”** means a formulation not containing any bulk drug specified in the First Schedule;
- **“pre-tax return”** means profits before payment of Income-tax and surtax and includes such other expenses as do not form part of the cost of formulation;
- **“price list”** means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list;
- **“retail price”** means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price;
- **“retailer”** means a dealer carrying on the retail business of sale of drugs to customers;
- **“Scheduled bulk drug”** means a bulk drug specified in the First Schedule;
- **“Scheduled formulation”** means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name;
- **“sale turn-over ”** means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied retail price inclusive of sales tax, if any, paid or direct sales by the manufacturer or importer but does not include excise duty and local taxes, if any;
- **“Schedule”** means a Schedule annexed to this Order;
- **“wholesaler”** means a dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities of drugs.