

Drugs and Cosmetics Act 1940 and Rules 1945

EBC's Bare Act

DRUGS AND COSMETICS ACT, 1940

along with

DRUGS AND COSMETICS RULES, 1945

together with

**State Amendments
Subject and Product Index**



Third Edition

CONTENTS

- Schedules to the act and rules
- Salient features of the act

SCHEDULES TO THE ACT

- **First schedule** – Names of **books** under **Ayurvedic** and **Siddha** systems
- **Second schedule** – **Standard to be complied** with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution

SCHEDULES TO THE RULES

TYPE	CONTENT
“A”	Performa for forms no. 1 to 50 (Application, issue, renewal, etc.)
“B”	Rates of fee for test or analysis by CDL or Govt. analysts
“C”	List of Biological and special products (Injectable) applicable to special provisions. Ex. Sera, Vaccines, Penicillin.....etc
“C ₁ ”	List of Biological and special products (nonparenteral) applicable to special provisions. Ex. Digitalis, Hormones , Ergot
“D”	List of drugs that are exempted from provisions of import
“E ₁ ”	List of poisonous substances under the Ayurvedic , Siddha and Unani systems
“F”	Provisions applicable to blood bank

SCHEDULES TO THE RULES

TYPE	CONTENT
“F ₁ ”	Special provision applicable to biological and special products, eg. Bacterial and viral vaccines, sera from living animals, bacterial origin diagnostic agents
“F ₂ ”	Standards for surgical dressings
“F ₃ ”	Standards for umbilical tapes
“FF”	Standards for ophthalmic preparations
“G”	List of substances required to be used under medical supervision and labelled accordingly Ex. Metformin, Anti Histaminic, ...etc
“H”	List of substances (prescription) that should be sold by retail only on prescriptions of R.M.P. Ex. Atenolol, Lorazepam, Dapson ...etc

SCHEDULES TO THE RULES

TYPE	CONTENT
“J”	List of diseases and ailments that drug should not claim to cure Ex. Cancer, AIDS, Cataract, Diabetes...etc
“K”	List of drugs that are exempted from certain provisions regarding manufacture
“M”	Requirements of manufacturing premises, GMP requirements of factory premises, plants and equipments
“M ₁ ”	Requirements of factory premises for manufacture of Homeopathic medicines
“M ₂ ”	Requirements of factory premises for manufacture of cosmetics
“M ₃ ”	Requirements of factory premises for manufacture of medical devices
“N”	List of equipment to run a Pharmacy
“O” 4/2/2012	Standards for disinfectant fluids Ex... Phenol, H ₂ O ₂ , alcohol....

SCHEDULES TO THE RULES

TYPE	CONTENT
“P”	<i>Life period(expiry) of drugs</i> Ex. Insuline Inj. – 24 months
“Q”	<i>Coal tar colors</i> permitted to be used in cosmetics Ex. Caramel, TiO ₂ , Toney red.....
“R”	Standards for <i>mechanical contraceptives</i>
“R ₁ ”	Standards for <i>medical devices</i>
“S”	Standards for <i>cosmetics</i>
“T”	Requirements (GMP) of factory premises for <i>Ayurvedic, Siddha, Unani</i> drugs
“U”	Manufacturing and analytical records of <i>drugs</i>

SCHEDULES TO THE RULES

TYPE	CONTENT
“U ₁ ”	Manufacturing and analytical records of cosmetics
“V”	Standards for patent or proprietary medicines
“W”	List of drugs marketed under generic names- Omitted
“X”	List of narcotic drugs and psychotropic substances EX. Opium, Morphine, Barbitol.....
“Y”	Requirement and guidelines on clinical trials for import and manufacture of new drugs

DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

Salient features of the Act:-

- Substantial **enhancement in punishment**
- **Life imprisonment** for offenders involved in manufacture, sale and distribution of spurious and adulterated drug likely to cause **grievous hurt**
- **Minimum** punishment of **seven years** which may extend to life imprisonment
- Provision for compensation to affected person

DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

Salient features of the Act:-

- Corresponding enhancement in punishment for **repeated offenders**
- **Cognizance** can be taken on the complaint of any gazetted officer authorized by Central or State Government
- Cases to be tried by **Sessions Court**

DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

Salient features of the Act:-

- Designation of **special courts** for trial of offences in respect of adulterated and spurious drugs
- All offences relating to adulterated and spurious drugs made **cognizable and non bailable**
- Restrictions on bail – **Bail cannot be granted** unless public prosecutor is heard
- Certain offences made **compoundable**

References

- Available on www.cdsco.nic.in
- “Pharmaceutical Jurisprudence” by Dr.G.K.Jani; Atul prakashan; Fifth edition(2005-06); 28-133.
- Forensic Pharmacy by C.K. Kokate and S.B. Gokhle; Published by Pharma Book Syndicate; 152.

THANK YOU

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- (a) Describe the functions of Central Drug Laboratory.
 - (b) Sale of drugs according to drugs and cosmetic Act.