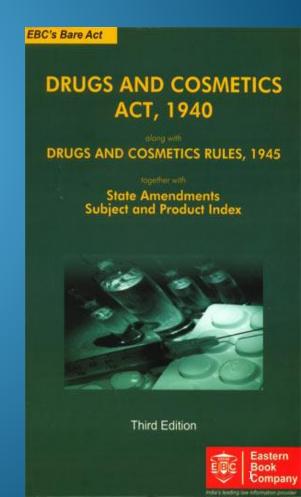
# Drugs and Cosmetics Act 1940 and Rules 1945



## CONTENTS

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

2

### 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

CONTENT

"B"	Rates of fee for test or analysis by CDL or Govt. analysts
"C"	List of <b>Biological and special products (Injectable)</b> applicable to special provisions. Ex. Sera, Vaccines, Penicillinetc
"C <sub>1</sub> "	List of Biological and special products (nonparenteral) applicable to special

List of drugs that are **exempted** from provisions of **import** 

Performa for forms no. 1 to 50( Application, issue, renewal, etc.)

List of poisonous substances under the Ayurvedic, Siddha and Unani systems Provisions applicable to blood bank 4/2/2012

Ex. Digitalis, Hormones, Ergot

provisions.

**TYPE** 

"A"

"D"

"E,"

TYPE	CONTENT
"F <sub>1</sub> "	Special provision applicable to biological and special products, eg. Bacterial and viral vaccines, sera from living animals, bacterial origin diagnostic agents
"F <sub>2</sub> "	Standards for <b>surgical dressings</b>
"F <sub>3</sub> "	Standards for <b>umbilical tapes</b>
"FF"	Standards for <b>ophthalmic preparations</b>
"G"	List of substances required to be used under medical supervision and labelled accordingly Ex. Metformin, Anti Histaminic,etc
"H" 4/2/2012	List of substances (prescription) that should be sold by retail only on prescriptions of R.M.P. Ex. Atenolol, Lorazepam, Dapsonetc 5

TYPE	CONTENT	
"]"	List of <b>diseases and ailments</b> that drug should <b>not claim to cure</b> Ex. Cancer, AIDS, Cataract, Diabetesetc	
"K"	List of drugs that are <b>exempted</b> from certain provisions regarding <b>manufacture</b>	
"M"	Requirements of manufacturing premises, <b>GMP requirements</b> of factory premises, plants and equipments	
"M <sub>1</sub> "	Requirements of factory premises for manufacture of <b>Homeopathic medicines</b>	
$^{"}M_{_2}$ "	Requirements of factory premises for manufacture of cosmetics	
"M <sub>3</sub> "	Requirements of factory premises for manufacture of <b>medical device</b> s	
"N"	List of equipment to run a Pharmacy	
"O"	Standards for <b>disinfectant flui</b> ds Ex Phenol, H2O2, alcohol	

ТҮРЕ	CONTENT
"P"	<b>Life period(expiry)</b> of drugs Ex. Insuline Inj. — 24 months
"Q"	<b>Coal tar colors</b> permitted to be used in cosmetics Ex. Caramel, TiO2, Toney red
"R"	Standards for mechanical contraceptives
"R <sub>1</sub> "	Standards for <b>medical devices</b>
"S"	Standards for <b>cosmetics</b>
"T"	Requirements (GMP) of factory premises for Ayurvedic, Siddha, Unani drugs
"U" 4/2/2012	Manufacturing and analytical records of <b>drugs</b>

ТҮРЕ	CONTENT
"U <sub>1</sub> "	Manufacturing and analytical records of <b>cosmetics</b>
"V"	Standards for <b>patent or proprietary medicine</b> s
"W"	List of drugs marketed under generic names- Omitted
"X"	List of <b>narcotic</b> drugs and <b>psychotropic</b> substances EX. Opium, Morphine, Barbital
"γ"	Requirement and guidelines on <b>clinical trials</b> for import and manufacture of new drugs
	O C

# 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.



13

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