UNIT - I
CHAPTER -1

DRUG AND COSMETIC ACT

Points to be covered in this topic

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❑ INTRODUCTION

Drugs and Cosmetics Act was passed	**10th April 1940**	**By the Indian Legislature**
Rule passed	**1945**	
This Act was amended	**1955**	**By the Indian Parliament**
Subsequently amended	**1960, 1962, 1964, 1972, 1982, 1986, 1995, 2008, 2011 and 2018**	

❑ OBJECTIVES

- This is an act to regulate the **import, manufacture, distribution and sales of drugs.**
- Manufacture, distribution and sale of drugs and cosmetics by **qualified persons only.**
- To prevent **substandard** in drugs.
- To regulate the manufacture and sale of **Ayurvedic, Siddha and Unani drugs.**
- The act also provide for the **control over the manufacture, sale & distribution** of **Ayurvedic, Siddha, Unani & Homeopathic drugs.**

❑ DEFINITIONS

Drug	**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**

Cosmetic	Any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or otherwise applied to human body or any part thereof for cleans ing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as a component of cosmetic which does not include soap.
Misbranded drugs	1. If it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value. 2. If it is not labelled in the prescribed manner. 3. If its label or container or anything accompanying the drug bears any statement, design which makes any false claim for the drug.
Adulterated drugs	1. If it consists, in whole or in part, of any filthy, putrid or decomposed substance. 2. If it has been prepared, packed or stored under insanitary conditions whereby it may have been rendered injurious to health. 3. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
Spurious drugs	1. If it is imported under a name which belongs to another drug. 2. If it has been substituted wholly or in part by another drug or substance. 3. If it purports to be the product of a manufacturer of whom it is not truly a product.

Misbranded cosmetics	1. It contains a colour which is not prescribed. 2. It is not labelled in the prescribed manner. 3. Label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.
Spurious cosmetics	1. If it is manufactured under a name which belongs to another cosmetic. 2. If the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist. 3. If it purports to be the product of a manufacturer of whom it is not truly a product.
Ayurvedic, Siddha or Unani drug	All medicines intended for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the first Schedule.
Drug Inspector	A Drug Inspector appointed by the Central or a State Govt who is an expert and qualified to monitor the safety, utility, efficacy and quality of a drug from its manufacturing till its sale at the retail shop.
Drug Store	Licensed premises for the sale of drugs, a retail store which do not require the services of a qualified person and sells both prescription and non-prescription drugs.
Pharmacy	Licensed premises for the sale of drugs, which require the services of a qualified person but where the drugs are not compounded against prescriptions.
Qualified Person	1. He is a person holding diploma or degree in Pharmacy or Pharmaceutical Chemistry. 2. Registered pharmacist, (under Pharmacy Act, 1948). 3. Has minimum 4 years experience of dispensing and has been approved by licensing authority as a 'Qualified Person' on or before 31st Dec 1969.

Government Analyst	Appointed by the Central or State Govt. who shall analyse or test or cause to be analysed or tested such samples of drugs as may be sent to him by Inspectors or any other persons or authority authorised by the Central or a State Govt. and reports of the results.
Manufacture	In relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug or the packing of any drug or cosmetic, in the ordinary course of retail business.
Patent or Proprietary Medicine	In relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha of Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books.
Homeopathic Medicines	It includes any drug and whose therapeutic efficacy has been established through long clinical experience as recorded in authoritative Homeopathic literature, prepared according to the techniques of Homeopathic pharmacy. It does not include medicines, administered by parenteral route.

❑ SCHEDULES TO THE ACT AND RULES

Schedules to the Act

FIRST SCHEDULE	SECOND SCHEDULE
Names of books under Ayurvedic, Siddha **and Unani** Tibbs systems.	**Standard to be compiled** with by imported drugs and by drugs manufactured for sale, **stocked, or** exhibited for sale or distributed.

Schedules to the Rules

Sr. No.	SCHEDULES	SIGNIFICANCE
1	A	**Forms** and formats of letters for applications of **licensing** etc.
2	B	**Fee** structure for drug analysis by **CDL** or by the Govt. Analyst.
3	C	Biological and special products for **parenteral administration** whose import, manufacture, sale and distribution are governed by special provisions. Eg. Surgical dressings and ophthalmic preparations etc.
4	C_1	Other special products for **non-parenteral** administration whose import, manufacture, sale and distribution are governed by special provisions. Eg. Digitalis, Ergot , Adrenaline, Fish liver oil etc.
5	D	Drugs **exempted** from the provision of **import of drugs.**
6	E_1	**Poisonous** substances under Ayurvedic, Siddha and Unani system of medicines.
7	F & F_1	Special provisions applicable for the production, testing, storage, packing and labelling of **biological and other special products.**
8	F_2	Standards of **surgical** dressings.
9	F_3	Standards of sterilized **umbilical** tapes.
10	FF	Standards for **ophthalmic** preparations.

Sr. No.	SCHEDULES	SIGNIFICANCE
11	G	Various drugs/ substances to be used under the **medical supervision** and which are to be labelled accordingly.
12	H	Various drugs to be sold on the **prescription of an RMP.**
13	J	Various **ailments** (diseases) **that cannot be treated** by any drug currently in market.
14	K	Drugs **exempted** from provisions related to **manufacture of drugs.**
15	M	Requirements of **Good Manufacturing practices (GMP)** and **factory premises** and the requirements of **plant and equipments.**
16	M_1	Requirements for factory premises, etc. for the **manufacture of Homeopathic drugs**.
17	M_2	Requirements for factory premises for the **manufacture of cosmetics**.
18	M_3	Requirements for factory premises for the **manufacture of medical devices**.
19	N	List of manufacture **equipments for the efficient running of a pharmacy.**
20	O	Standard for **disinfectant fluids**.
21	P	**Life period** and storage of various drugs.
22	P_1	Regulations regarding **retail package size** of various drugs.
23	Q	List of **permitted dyes** and coal tar colours in cosmetics.
24	R	Standards for **condoms** and other **mechanical contraceptives.**
25	R_1	Standards for **medical devices.**
26	S	Standards for **cosmetics.**
27	T	**Requirements for factory premises and manufacture** of Ayurvedic, Siddha and Unani products.

Sr. No.	SCHEDULES	SIGNIFICANCE
28	U	Maintenance of manufacturing and analytical **records of drugs.**
29	U_1	Maintenance of manufacturing, raw material and analytical **records of cosmetics.**
30	V	Standards for **patent and proprietary** medicines.
31	W	List of drugs which can be marketed under **generic names** only.
32	X	List of drugs which are **habit forming, psychotropic** and other drugs likely to be misused for addictive purposes.
33	Y	Requirement and guidelines for **clinical trials.**

❑ IMPORT OF DRUGS

❖ Prohibition of Import of Certain Drugs or Cosmetics:

1. Any drug or cosmetic which is **not of standard quality.**
2. Any **misbranded** or **spurious** or **adulterated** drug or cosmetics.
3. Any drug or cosmetic **without import license**, for the import, for which an import license is prescribed.
4. Any **patent or proprietary medicine**, which has not displayed the true formula.
5. Any drug which **claims to cure or prevent** any disease or ailments specified in **Schedule J.**
6. Any cosmetic or drug containing any ingredient, which is **unsafe or harmful.**
7. Any drug or cosmetic whose **manufacture, sale, distribution and import of which is prohibited by rule** made under this act, EXCEPT for the purpose of examination, test or analysis.
8. Drugs **not labelled** in the prescribed manner.
9. Drugs **after the expiry**, and those which **does not meet the standards, quality and purity** specified in the **schedule F.**

❖ Import of drugs under licence or permit:

1. Drugs specified in **schedule C and C_1 excluding those specified in schedule X.**
2. Drugs specified in **schedule X.**
3. **Small quantities of drugs imported** for the **purpose of examination, test or analysis.**
4. Drugs for **personal use** covered by a prescription of RMP.
5. Any **new drug.**
6. An application for import licence should be made to the proper authority in the prescribed form.
7. A **licence remains valid upto 31st December of the year** following the **year in which it was granted, unless suspended or cancelled earlier.**
8. A fee of **250** shall be paid for a **duplicate copy of license**, if the **original is defaced, damaged or lost.**

SR. NO.	TYPE OF IMPORT LICENSE	FORM NUMBER	
		APPLICATION	LICENSE
1	Drug other than Schedule X drugs	8	10
2	Schedule X drugs	8A	10A

A. Registration Certificate:

- Certificate issued under Rule 27-A, by the licensing authority in **Form-41**
- A fee of 1,000 shall be paid through a challan along with the application in **Form 40.**

B. Suspension and Cancellation:

Import License and Registration Certificate will be suspended or cancelled, if **the manufacturer or licensee fails to comply with any of the conditions.**

➢ The reasons for the cancellation may be:

i. The drugs in the schedule C and C_1 are prohibited for import into the country after the expiry of potency of the drug product.

ii. If the drug is banned in the country of origin then it is prohibited from importing into the country EXCEPT for the purpose of examination, test or analysis.

❖ Import of New Drugs:

- **Written permission of the licensing authority(LA).**
- For obtaining **permission, all documentary related to the standards of quality, purity and strength** etc. should be supplied to the LA.
- An **application for an import License for small quantities of a new drug,** in **rule 122-E** for the purpose of treatment of patient.
- Every **application in Form 12-AA** shall be accompanied by a fee of **100 Rs. for a single drug** and an **additional fee of 50 Rs. for each additional drug** and fees shall be paid through a challan from bank.
- A **License for import of small quantities** of a new drug, defined in rule 122-E, for the purpose may be cancelled by the LA for the conditions subject to which the License was issued. If so, the licensee may appeal to the Central Govt. within 3 months of the date of the order of cancellation.

❖ Conditions of Import License:

- Licensee must observe at all the times the undertaking given in **Form 9.**
- Licensee must allow any authorized Inspector to:
  - **(i) Enter the licensed premises where imported drugs are stored.**
  - **(ii) Inspect the substances employed for testing.**
  - **(iii) Take samples.**

- The licensee must furnish the adequate quantity of sample from the required batches to the LA for **examination along with complete protocols of the test applied.**
- If LA so directs, until receipt of Certificate of Authorization, the licensee must **not sell any batch products to which samples are submitted to the licensing authority.**
- The licensee must **maintain the record** of all sales of imported substances as **prescribed under the rules**, and should **furnish the same during the inspection.**
- The licensee must **maintain separate records** for the **sale or distribution of Schedule-X drugs.**
- Licensee must also **comply with such further requirements**, prescribed by the authority and of which he **has been given not less then four months of notice.**

❖ Drugs Imported for examination, test or analysis:

- License a under **Form-11.**
- Drug must be **examined in the place specified in the license** by the licensing authority.
- An authorized inspector must be allowed to **investigate the manner in which imported substances are used** and thereof allowed to take the samples.
- The **record of the imported substances** along with their quantities, the date of importation and the name of manufacturer should be maintained and reported to the authority.
- The **licensee must comply with any further requirements** as may be specified by the authority, and of which the **licensing authority has given, to him not less than notice of a month**.
- If the **license is cancelled**, the licensee may appeal to the Central Government within three months of the date of the order of cancellation.

❖ Drugs imported for personal use:

- Drugs or cosmetics must be a **part of a passenger's bonafide baggage** and must be **intended for the exclusive personal use of the passenger**.
- They must be **declared to the custom collector**, if so directed.
- The quantity of any single drug so imported must **not exceed hundred average doses.**
- Any drug or cosmetic **not forming the part of passenger's baggage**, may be allowed to import to an **application made to the licensing authority in form 12-A.**
- If the licensing authority is satisfied, a permit is **granted in Form 12-B**.

❖ Exempted drugs (schedule D):

CLASS OF DRUGS	EXTENT AND CONDITIONS OF EXEMPTION
Substances not intended for medicinal use	Can be imported without any restriction provided imported in bulk and the importer certifies that it is imported for non-medicinal uses. If imported otherwise then in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use.

Substances included in schedule C, required for manufacturing purposes but not intended for medicinal use	Exempted from all provisions regulating import except that the importer should be holding licence for manufacture of schedule C and C_1 drugs.
Substances used both as drugs as well as articles of food e.g. milk powder, spices, pre digested food, etc.	Exempt from all provisions regulating import.

❖ Permitted places for import into India:

By rail	i. Ferozepur Cantonment and Amritsar Railway Stations: (across the frontier with Pakistan) ii. Ranaghat, Bongaon and Mohiassan Railway Stations: (across the frontier with Bangladesh)
By sea	Chennai, Calcutta, Mumbai and Cochin
By air	Chennai, Calcutta, Mumbai, Delhi and Ahmedabad
By road	Raxual for drug from Nepal

❖ Offences Relating to Import of Drugs:

S.NO.	OFFENCE	PENALTY	
		First conviction	Second conviction
1	Import of adulterated or spurious drugs or spurious cosmetic or any cosmetics containing any ingredient which may render it unsafe or harmful for use under the directions recommended.	Upto 3 years / fine upto Rs 5,000.	Upto 5 years / fine upto Rs 10,000 or both.
2	Import of any drugs or cosmetic other than referred above; the import of which is prohibited	Upto 6 months / fine upto Rs 500 or both.	Upto 1 year / fine upto Rs 1000 or both
3	Import of any drug or cosmetic in contravention of any notification issued under section 10A.	Upto 3 years /fine upto Rs 5,000.	

❑ MANUFACTURE OF DRUGS

❖ Prohibition of Manufacture and Sale of Certain Drugs

1. Any drug and cosmetic which is not of a standard quality or is **misbranded, adulterated or spurious.**
2. Any **patent or proprietary medicine**, whose formula with the quantities, is not disclosed on the label or container.
3. Any drug which purports or claims to prevent, cure or mitigate any such disease specified in **schedule J.**
4. Any cosmetic containing any ingredient which may render it **unsafe or harmful for use.**
5. Any drug or cosmetic in **contravention** of this act or rules made there under .

❖ Conditions for Grant of License

1. The manufacture must be conducted under active direction and **personal supervision of competent technical staff** (approved manufacturing chemist).
2. The licensee and factory premises should comply with **the conditions and requirements prescribed** under **Schedule M** respectively.
3. The applicant must provide for **various operations, adequate space, plant and equipment,** as per **Schedule M.**
4. The applicant must provide separate testing unit or quality control section with an, independent head, with adequate facilities, for the **test and standardization of drugs and raw materials.**
5. The applicant should make adequate **arrangements for the storage of drugs, manufactured.**
6. For **patent and proprietary medicines**, the applicant must **furnish the documents and data related to claims, safety, stability, therapeutic justifications** etc. as per the rules.

❖ Types of Licenses for Manufacture of Drugs

Sr. No.	Classes of Drugs	Form of Application	Form of License	Certificate of Renewal of licence
1	Other than Schedule C, C1 and X	24	25	26
2	Schedule X	24-F	25-F	26-F
3	Schedule C and C_1	27	28	26
4	Schedule C, C_1 and X	27-B	28-B	26-F
5	Loan License (other than Schedule C, C_1 and X)	24-A	25-A	26-A
6	Loan License (only Schedule C, C_1)	27-A	28-A	26-A
7	Repacking License (other than Schedule C, C_1 and X)	24-B	25-B	26-B
8	Large volume parenteral, sera and vaccines	27-D	28-D	----

❖ Conditions of License for Manufacture of Drugs

➢ Manufacture of Schedule C, C1 and X Drugs:

- Conditions of license

Schedule C, C_1 and X drugs	Form 28-B and 28-D
Other than schedule C and C_1 drugs	Form 25
Schedule X drugs	Form 25-F

SR. NO.	LICENSE MUST
1	Provide and maintain staff, premises and equipments (as per schedule M and schedule M_3 for medical devices).
2	Test raw materials and final products of each batch either in the laboratory approved by the LA.
3	Maintain records of manufacture and testing of each batch as per schedule U.
4	Allow drug inspector to enter and inspect, premises, plant, process of manufacture, means of standardization and tests.
5	Provide the required information to drug inspector for ascertaining compliance for provisions of Act and rules.

SR. NO.	LICENSEE MUST
6	**Time to time** report to the licensing authority: i. Changes in expert staff responsible for manufacture or testing. ii. Material alterations in premises or plant. iii. Samples of desired drugs and complete protocols of tests applied
7	**Not sell** any batch, sample of which is submitted to the licensing authority, until receipt of Certificate of authorization is issued.
8	**Withdraw** from sale remainder of any batch or recall drugs **already issued,** if licensing authority directs to do so.
9	**Not sell any drug manufactured** under the license unless due precautions, necessary for preserving its properties, are taken throughout the period after manufacturing, also must maintain such quantities of reference samples.
10	**Comply with the provisions** of Drugs and Cosmetics Act, 1940, rules thereunder and such further requirements time to time.
11	Maintain **an "Inspection Book"** in **Form 35**, to record impressions and defects noticed by Drug Inspectors.
12	**Comply with requirements** of "Good Manufacturing Practices" as per schedule M.
13	The licensee having license to manufacture schedule C, C_1 and X drugs in **Form 28-B** must, (i) **Forward to the LA every 3 months**, a statement of sale to the manufacturers, wholesalers, retailers, hospitals, dispensaries, nursing homes, and RMP. (ii) **Maintain as prescribed** under rules, accounts of all transactions as regard to use, stock, manufacture, storage and sale of schedule X drugs. (iii) **Store always schedule X bulk drugs separately** under custody of a responsible person.

Manufacture of Drugs for Test, Examination and Analysis:

1. A license is required to manufacture any **drug in small** quantity for this purpose.
2. If a person proposing to manufacture does not hold a license to manufacture drugs in Schedule C and C_1 or other than Schedule C, C_1 and X, shall obtain a **license Form 29** before manufacturing such drugs.
3. Drugs which are **unsafe** for use, a license in **Form 29 can be granted only on producing NOC** (no objection certificate) from the LA.
4. Application must be **countersigned by the Head of the Institution**, which proposes to undertake the manufacture.
5. License remains **valid for a period of 1 year**, unless cancelled or suspended.
6. Any **drug for the examination**, shall be placed in the containers, labelled for the purpose of manufacturing. Thereafter supplied to the any other manufacturer, when necessary.
7. The licensee shall keep a record the quantity of drugs supplied for analysis also maintain **'Inspection Book'.**

Manufacture of New Drugs (Rule 122 E) :

1. A **new substance** of chemical, biological or biotechnological origin or in bulk or prepared dosage form etc. which except during local clinical trials **has not been used in the country** and **recognised in the country as effective and safe.**
2. Following provisions are applicable to the manufacture of a new drug whether classifiable under Schedule C and C_1 or otherwise:
   i. **No 'new drug'** can be manufactured unless prior approval of the LA is taken.
   ii. Applicant should produce all documentary and other **evidence relating to the standards of quality, purity, strength** and such other information as may be required including the results of **therapeutic trials carried out on the 'new drug'.**
   iii. While applying for a licence to manufacture a 'new drug' or its preparations an applicant should produce alongwith his application **evidence that the drug has already been approved.**
3. **Schedule Y** to the Drugs and Cosmetics Rules provides for the **clinical trials for manufacture of new drugs** (described under import of the new drugs).

❑ LOAN LICENSE

1. It is **issued by the LA**, to a person **who does not own, arrangements for manufacture** but intends to avail the manufacturing facilities owned by another licensee.
2. A separate license shall be issued in case drugs are sold at more than one place.
3. The LA, before the grant of a loan licence, satisfy that the **manufacturing unit has adequate equipment, staff, capacity for manufacture**, etc. to undertake the manufacture on behalf of the applicant for a loan licence.
4. Application for manufacture of more than 10 items for each category of drug on a loan licence shall be accompanied by an **additional fee of Rs. 300 per additional item specified in Schedule M and Schedule M_3.**
5. Maintain **'Inspection Book' in Form 35.**
6. Licensee shall test each batch of raw materials used and the final product and also maintain the **records of manufacture and testing of each batch as per schedule U.**
7. Maintain the reference **samples for the period of 3 years.**
8. For **Schedule C and C_1 drugs**, the licensee shall **furnish the data** of stability and date of expiry to the **licensing authority.**
9. If the licensing authority is satisfied that a loan licence is defaced damaged or lost or otherwise rendered useless, he may, on payment of a **fee of Rs. 1000 , issue a duplicate licence.**

Sr. No.	Classes of Drugs	Form of Application	Form of License
1	Loan License (other than Schedule C, C_1 and X)	24-A	25-A
2	Loan License (only Schedule C, C_1)	27-A	28-A

❑ REPACKING LICENSE

SR. NO.	CLASSES OF DRUGS	FORM OF APPLICATION	FORM OF LICENSE
1	Repacking License (other than Schedule C, C1 and X)	24-B	25-B

1. Repacking of drugs should be conducted under hygienic conditions under **personal supervision of competent person**, approved by the LA.
2. Maintain **adequate arrangements for carrying out tests of drugs repacked**, in the specified place by the authority.
3. The licensee shall allow **Inspector to inspect the premises and to take samples of repacked drugs.**
4. Maintain the records of manufacture and testing of each batch as per schedule U.
5. Records must be **retained for 5 years from the date of repacking.**
6. Shall **maintain the reference samples from each batch of repacked drugs**, for the specified period.
7. Licences **remain valid for a period of 5 years** from the date its granted or renewed, unless suspended or cancelled.