UNIT-I

DRUG AND COSMETICS ACT, 1940 AND ITS RULES 1945:

Objectives:- The drug & Cosmetic Act was passed in 1940, with the main object to regulate the import, manufacture, distribution and sale of drug & Cosmetics through licensing.

⇒ The act regulates the import of drugs in india, so that no substandard or spurious drug will enter into our Country.

⇒ The act prohibits the manufacture of substandard or spurious drug in the Country.

⇒ The act provide for the Control over the sale & distribution of drugs by only trained & qualified persons.

⇒ The act also provide for the Control over the manufacture, sale & distribution of Ayurvedic, Siddha, Unani & Homeopathic drugs.

Introduction to Pharmaceutical Jurisprudence:—

Forensic Pharmacy or Pharmaceutical Jurisprudence is that branch of Pharmacy which deals with various legislation related to drug and Pharmaceuticals and profession of Pharmacy.

The word forensic is derived from latin term forencis means a forum, a place for interaction or deliberations.

Jurisprudence means study of fundamental laws and in case of Pharmaceutical Jurisprudence, it is law relating to Pharmacy.

Jurisprudence derived from two Latin words

⇒ Juris — law

⇒ Prudentia → Wisdom → wisdom of law
→ Knowledge → Knowledge of law
→ Philosophy → Philosophy of law
→ Science → Science of law

History of Drug Legislation in India :—

⇒ The government of India is pursuance the resolution appointed a Committee known as the Drug Enquiry Committee in 1928

⇒ The Indian Journal of Pharmacy was started by Prof. ML Schroff in 1939

⇒ All India Pharmaceutical Congress associated in 1940. The Pharmaceutical Conference held its sessions at different places to ~~publicity~~ publicize Pharmacy as a whole.

⇒ Government of India on 11th August 1930, appointed a Committee under the chairmanship of Late Col. R.N. Chopra to see in to the problems of Pharmacy in India and recommended the measures to be taken.

The drug and Cosmetics Act and Rules :— The Drug are Vital to the Health of an individual but Cosmetics do hot play any role in our Health.

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⇒ Act Covers the drugs under allopathic ayurvedic Homeopathic and Unani Tibb system as well as drug for veterinary use.

⇒ The main object of the Act is to prevent substandards in drugs. It is a life saving statute and extends to whole of India.

Drug & Cosmetic (Amendment) - 1955, 1960, 1962, 1964, 1972, 1982, 1995 2008

Definitions :—

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"Ayurvedic, Siddha or Unani drugs" include all medicines intended for internal or external use for 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 of the Act.

⇒ Central licence approving Authority means the drug Controller, India appointed by Central Government.

Cosmetic means any article intended to be rubbed, Poured sprinkled or sprayed or introduced in to or otherwise applied to the human body.

Misbranded Drugs :—
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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.

⇒ if it is not labelled in the prescribed manner.

⇒ if its label or Container or anything accompanying the drug bears any statement design or device which makes any false claim for the drug or which is false or misleading in any particular.

Adulterated Drugs :— if it has been prepared, packed
——xxx—— or stored under insanitary Condition whereby it may have rendered injurious to Health.
if any Substance has been mixed there with so as to reduce its quality or strength.

Spurious Drugs :— if it is imported (manufacture, sale and
——xxx—— distribution of drug) under a name belong to another drug.

⇒ if the label or Container bears the name of an individual or Company purporting to be the manufacture of the drug which individual or Company is fictitious or does not exist.

Misbranded Cosmetics :—

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⇒ if it Contains a Colour which is not prescribed
⇒ if it is not labelled in the prescribed manner
⇒ if the label or Container or anything accompanying the Cosmetic bears any statement which is false or misleading in any particular.

Spurious Cosmetics :—

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⇒ if it is manufactured under a name which belongs to another Cosmetic
⇒ if it purports to be the product of a manufacturer of whom it is not truly a product.
⇒ if the label or Container bears the name of an Individual or Company purporting to be the manufacturer of the Cosmetic which individual or Company is ~~for~~ fictitious or does not exist.

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Legal definitions of Schedules to the act and rules

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Schedules to the Act :—

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First Schedule— Name of Books Under Ayurvedic, Siddha and Unani Tibb System.

Second Schedule— Standard to be Complied with by imported drugs and by drugs manufactured for sale, stocked or exhibited for sale, sold or distributed.

In addition, the following appendices are also prescribed.

Appendix I- Data required to be submitted with application for permission to market a new drug.

Appendix II- Format for submission of clinical trial reports.

Appendix III- Animal toxicity requirements for clinical trials and marketing of a new drug.

Appendix IV- Number of animals for long term toxicity studies.

Appendix V- Patient Consent form for participation in a Phase I Clinical trial.

Appendix VI- Four groups of fixed dose Combinations and their data requirements.

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Schedule to the Rules :—

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Schedule - A	Schedule-FF	Schedule-Q
Schedule - B	Schedule-G	Schedule-R
Schedule - C	Schedule-H	Schedule-R_1
Schedule - C_1	Schedule-J	Schedule-S
Schedule - D	Schedule-K	Schedule-T
Schedule - D_1	Schedule-M	Schedule-U
Schedule - D_2	Schedule-M_1	Schedule-U_1
Schedule - E_1	Schedule-M_2	Schedule-V
Schedule F	Schedule-M_3	Schedule-W
Schedule F_1	Schedule-N	Schedule X
Schedule F_2	Schedule-O	Schedule-Y
Schedule F_3	Schedule-P	
	Schedule-P_1	

Import of Drugs

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In general drugs or Cosmetic may be imported into India under the authority of a licence excepting those whose import is prohibited.

Some drugs or Cosmetics can be imported without any permit provided they are of standard quality and statement that they comply with the provisions relating to import has been given to the Customs Collector by the

manufacturer or importer.

By implication the word import includes the carrying of the goods across the customs frontier in the same state.

Prohibition of import of Certain drugs or Cosmetics:—

From the date fixed by the Central Government by notification in the official Gazette, no person can import—

⇒ any drug or Cosmetic which is not of standard quality.

⇒ any misbranded or spurious or adulterated drug.

⇒ any misbranded or spurious Cosmetic.

⇒ any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or Container thereof the true formula or list of active ingredient Contained in it.

⇒ any Cosmetic Containing any ingredient which may render it unsafe or harmful for use under the direction indicated or recommended.

⇒ drugs which claim to prevent or cure any of the diseases or ailments specified in Schedule J to the Rules.

⇒ Drugs whose manufacture, sale and distribution are prohibited in the Country of origin, except when required

for the purpose of examination, test or analysis.

⇒ drugs not labelled and packed in the prescribed manner

⇒ biological and other special products specified in Schedule C and C_1 after the date of their expiry as marked on the label or those not complying with the standard of strength quality and purity as may be specified.

⇒ Any new drug except with express permission of the LA. (LA = Licensing Authority)

Import of drugs under licence or permit :—

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⇒ drugs specified in Schedule C and C_1 excluding those specified in Schedule X

⇒ drugs specified in Schedule X

⇒ Small quantities of drugs imported for the purpose of examination test or analysis.

⇒ drugs imported by a Government hospital for treatment of patients.

⇒ Drugs for personal use covered by a prescription of Registered medical practitioner

⇒ Any new drug.

Conditions of import Licence:—

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⇒ The manufacturer must observe at all times the undertaking given by him or on his behalf in form 9

⇒ The Licencee must allow any authorised Inspector to enter any premises where the imported substance is stocked, to inspect the means, if any, employed for testing the substances and to take samples;

⇒ The licencee should furnish a sample adequate for examination as required by the Licensing Authority

a) Import of fixed dose Combination drug:— The LA after being satisfied that the fixed dose combination to imported shall be effective and safe for use in the Country, shall issue permission in form 45 or form 46, subject to the conditions stated therein.

b) Import of Schedule C, C_1 and x drugs:— An import licence is required for the import of any biological or other special product specified in Schedules C and C_1 excluding x and drugs specified in Schedule x.

c) Import of Drugs for examination test or Analysis:—

⇒ Drugs Can be imported only under a licence in Form 11.

⇒ The substances imported should be used exclusively for the purpose of examination, test or analysis in the place specified or in any other place authorised by the LA.

⇒ The licencee must allow any authorised Inspector to enter and inspect the premises, and to investigate the manner in which the substances are being used and to take samples thereof,

d) Import of drugs for Personal use :—

⇒ The drug is for bonafide personal use

⇒ The quantity is reasonable and covered by a prescription from registered medical practitioner

⇒ a permit is granted in respect of the said drug in form 12-B

e) Import of drugs by Govt. hospital/ autonomous medical institution for treatment of patients— Application for such import is to be made in form 12 AA.

f) Import of New drugs—No New drug ~~means~~ Can be imported except with the written permission of the LA. while applying for such a permission, all documentary and other evidence relating to the standards of quality, purity and strength etc. should be supplied to the LA.

Offence Relating to Import of Drugs.

Offence	First Conviction	Subsequent Conviction
Import of adulterated or spurious drugs or spurious cosmetic or any ingredient which may render it unsafe or harmful for use under the directions recommended	Imprisonment up to three years and fine up to Rs - 5000/-	Imprisonment up to five years or fine up to Rs-10000 or both
Import of any drugs or cosmetic other than referred above, the import of which is prohibited	imprisonment up to six months or fine up to Rs 500 or both.	Imprisonment up to one year or fine up to Rs - 1000 or both
Import of any drug or Cosmetic in Contravention of any notification issued under section 10 A.	imprisment up to 3 years or both fine up to Rs - 5000 or both.	

MANUFACTURE OF DRUGS

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Drug manufacturing is the process of Industrial-scale Synthesis of pharmaceutical drugs as part of the Pharmaceutical industry.

In relation to any drug or Cosmetic, includes any Process of part of a process for making, altering ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adapting any drug or Cosmetic with a view to its sale and distribution but does not include the compounding or dispensing of any drug or packing of any drug in the ordinary Course of retail business.

Following licences are provided for manufacturing of drugs Under the Drugs and Cosmetics Act and Rules thereunder-

⇒ Drugs other than those specified in Schedule C, C_1, and x

⇒ Drugs specified in Schedule C, C_1 but not specified in Schedule x

⇒ Drugs specified in Schedule C and C_1

⇒ Drugs specified in Schedule x but not in Schedule C and C_1

⇒ Drugs specified in Schedule C, C_1 and x

⇒ Drugs for the purpose of examination, test or analysis.

⇒ Loan Licences
⇒ Repacking Licences
⇒ Blood products

Prohibition of Manufacture and Sale of Certain Drugs.

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⇒ any drug which is not of standard quality or is misbranded, adulterated or spurious.

⇒ any Cosmetic which is not of a standard quality or is misbranded or spurious.

⇒ any patent or proprietary medicine whose formula is not disclosed on the label or Container.

⇒ any drug which purports or claims to prevent, cure or mitigate any disease specified in Schedule J.

⇒ any Cosmetic containing any ingredient which may render it unsafe or ~~hazf~~ harmful for use

⇒ any drug or Cosmetic in Contravention of this Act or Rules thereunder.

⇒ any drug or Cosmetic which has been imported or manufactured in Contravention of the provision of this act or rules there under or in Contravention of the Condition of a licence.

1] Manufacture of Drugs specified in Schedule C, C_1 and X

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Application for the licence to manufacture drugs specified in Schedule C, C_1 excluding those specified in Schedule X should be made to the LA or CLAA in form 27 and for manufacture of drugs specified in Schedule C, C_1 and X in form 27B. respective licenses are issued in form 28 and 28B.

Application for including any additional drug in the licence should be accompanied by a fee of Rs. 50 for each drug subject to a maximum of Rs-500.

2] Manufacture of Drugs other than those specified in Schedule C & C_1

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Application for the grant or renewal of a licence for the manufacture of drugs other than those specified in Schedule C, C_1 and X should be made to the LA in form 24 and for manufacture of Schedule X drugs in Form 24F.

The respective licences are issued in Form 25 and 25F.

3] Manufacture of Drugs for Examination, Test or Analysis

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A licence is necessary to manufacture any drug in small quantity for the purpose of examination, test or analysis.

4] Manufacture of New Drugs:—

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⇒ No New drug can be manufactured unless prior approval of the LA is taken

⇒ 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'

⇒ 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.

5] Loan Licences:— Loan licences are issued for the manufacture for sale or distribution of drugs other than those specified in Schedule C, C1 & X.
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Application for grant or renewal of such loan licence shall be made in Form 24-A and the licence shall be issued in Form 25A.

6] Repacking Licences:— Repacking licences are granted for the purpose of breaking up any drug other than those specified in Scheduled C and C1 on application to the LA in Form 24B and the licence is issued in Form 25B.
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Conditions for grant of licence in Schedule C, C_1 and X

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1) The manufacture will be Conducted under the active direction and personal supervision of Competent technical staff Consisting at least of one person who is a whole time employee and who is-

a) a graduate in pharmacy / Pharmaceutical Chemistry of a recognised university with at least 18 month's practical experience after graduation.

b) a graduate in science of a recognised university who passed his degree with chemistry or microbiology as a principal subject and had at least three years' practical experience in the manufacture of drug to which this licence applies after his graduation

c) a graduate in medicine from a recognised university with at least three years experience in the manufacture of relevant drugs.

d) a graduate in chemical engineering of a recognised university with at least three years practical experience in the manufacture of relevent drugs.

e) Holding any foreign qualification comparable in quality, content and training with above qualification and is permitted to work as Competent technical staff.

2] The factory premises should with the conditions prescribed in Schedule M and M_3 in respect of medical devices.

3] The applicant should provide adequate space, plant and equipment for any or all the manufacturing operations as prescribed in Schedule M and M_3.

4] The applicant should make adequate arrangements for the storage of drugs manufactured by him.

5] The applicant should furnish to the LA if required data on the stability of drugs which are likely to deteriorate, for fixing the date of expiry which shall be printed on the labels of such drugs on the basis of data so furnished.

6] The licencee shall comply with the requirements of Good manufacturing Practices laid down in Schedule M.

A licence in Form 28 or 28B remains valid for a period of 5 years on and ~~form~~ from the date on which it is issued.

Condition of licence for Manufacture of Drugs for Examination, Test or Analysis.

⇒ The drug should be used exclusively for the purpose for which they are manufactured.

⇒ The licencee should allow an Inspector to inspect the premises and satisfy himself that only examination, test or analysis is being conducted.

⇒ The licencee should keep a record of the quantity of drugs manufactured and supplied to any person.

⇒ The licencee should maintain an inspection book to enable an Inspector to record his impression and defects noticed.

⇒ The licencee must comply with any rules made subsequently and of which the LA has given him not less than one month's notice.