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Drugs and Cosmetics act 1940 and rules 1945 and new amendment –

Drugs and cosmetics act 1940 and its rules 1945 –

Objective — The drug and cosmetic act was passed in 1940 with main object to regulate the import, manufacture distribution and sale of drugs and cosmetics through licensing

- The act regulates the import of drugs in India. So that no sub-standard or spurious drug will enter in to our country.
- The act prohibit the manufacture of sub standard or spurious drug.
- The act provide for the control over the sale and distribution of drug by only trained and qualify person.
- The act also provide for the control over manufacture, sale and distribution of Ayurvedic, Siddha, Unani, homiopathic drugs.

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Introduction – The drugs are vital to the health of an individual but cosmetics do not play any role in our health.
Act covers the drugs under alopathic ayurvedic the and Unani System as well as the drug for veterin use.
The main objeet of the act this to prevent sub standards in drugs.
It is a life saving status and extene to whole of India.

Deffination – Ayurvedic Siddha or Unani drugs include all medicine intended for external or internal use for all in the diagnosis of ~~disorder~~ treatment medication or prevention of disease or disorder in human beings. or animals. and mfg exclusively in accordance with the formula described in the authoritative books of Ayurvedic Siddha. and Unani System of medicines specified in the 1st Shedule of the act.

Central licence. approving authority the drug Controller India appointed by Central government.

Cosmetics – Cosmetics means any articles intended to be rubbed, poured sprinkled or spread or introduced in to or otherwise apply to the human body.

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Miss branded drug - If it is so coloured coated powdered or polished that damaged is concealed or if it is made to appear or better if it is not labeled is prescribed a certain the drug bears any statement design or device which is false or misleading in any particular.

Adulterated drugs - If it has been prepared packed or stored under in sanitary condition were by it may have rendered injuries to health.

If any substance has been mixed their so as to reduce its quality or strength.

Spurious drugs - If it is imported (mfg) sale and distribution of drug under a name belong to another drug.

- If the label or container bears the name of an individuals or company purporting to be the mfg of the drug which individuals or company is fictitious or does not exist.

Miss-branded - Cosmetics - If it contain a colour which is not prescribed.

- If it is not labelled in the prescribed manner.

- If the label or container or anything accompaining the cosmetic bears any statement which is false mis leading in any particular.

Spurious Cosmetics - If it is mfg. under a named which belong to mother cosmetics. If it purports to be the product of a mfg of whom it is not truely a product.

If the label or container bears the name of an individuals or company purporting to be the mfg of the cosmetics which individuals or company is fictitious or does not exist.

Legal defination of schedules to be act & rules.

Schedules to the act -

① first schedules - Name of books under Ayurvedic, Siddha & Unani System.

② Second Schedule - Standard to be complied with by imported drugs and by drug mfg for sale, stoped or exhabited for sale sold or distributed.

- In edition the following appendixes are also perescribed.

① Appendixs 1st - Data required to be submitted with application for with permission - To market a new drug.

(ii) Appendix 2nd - format for submission of clinical trial reports.

(iii) Appendix 3rd - Animal toxicity requirements for clinical trials marketing of a new drug.

(iv) Appendix 4th — Numbers of animals for long term toxicity studies.

(v) Appendix 5th — patient consent form for participation in a phase I clinical trial.

(vi) Appendix 6th — appendix for groups of fixed dose combination and there data requirement

Import of drugs

In general drug or cosmetic may be imported in to India under the authority of the licence accepting those whose import is prohibited.

Some drugs or cosmetics can be imported without any permit provided they are of standard quality and declare that they comply with the provision relating to import has been given to the custom collector by the —

manufacturer or importer by implication the word import include the carrying of the goods across the custom frontier in the same state

prohibition of import of certain drug or cosmetics -

from the date fixed by central government by notification in the official gazettee no person can be import :

① Any drug or cosmetics which is not of standard quality.

② Any miss branded or spurious or adulterated drug

③ Any miss branded or spurious cosmetics.

④ Any patient 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.

⑤ Any cosmetics containing any ingredient which may render which it unsafe or harmful for use, under the direction indicated or recommended.

⑥ Drugs which claim to prevent or cure any of the disease or ailments specified in Schedule-J to the rules.

(7) Drugs whose mfg sale and distribution are prohibited in the country of origin, except when required for the purpose of examination, test of analysis.

(8) Drugs not labelled and packed in the prescribed manner.

(9) Biological & Special Other Special drugs / products specified in Schedule C and C1 after the date of their expiry as marked on the label are those not complaint with the standard of strength quality and purity as may be specified.

Import of drugs under license or permit —

- Drugs specified in Schedule - C and C1 excluding there specified in schedule - X.
- Drug specified in schedule - X.
- Small quantities of drugs imported for the purpose of examination test or analysis.
- Drugs imported by a gov. hospital for treatment of patient.

- Drugs for personal use covered by a prescription of registered medical practioner.

Condition of Import licence

- 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 stored to inspect the means if any employed for testing the substances and to take samples.
- The licencee should furnish a sample adiquate for examination as required by the licencing authority

Import of fixed drug dose combination drug.

The licencing authority 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 there in

Import of schedule C and C_1, and X drug

Import licence is required for -

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The import of any biological or other special product specified in Schedule C and C1 excluding - X and drugs specified in schedule - X

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 licencing authority.

The licencee must allow any authorised inspector to enter and inspect the premises and to investigate the manner in which the substances are being use and to take samples there off.

Import of drugs for personal use

The drug is for bonafied personal use. The quantity is reasonable and covered by a prescription from registered medical practicener.

A permit is granted in respect of the said drug in form 10 & B

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Import of drugs by government hospital autonomus medical institution for treatment of patients —

Application for such import is to be made in form 12 AA

Import of New drugs

No new drug can be imported accept with written permission of the licencing authority. while applying for such a permision, all documentary and other evidence. relating to the Standard of the quality, purity and strength should be supplied to the licencing authority

Offence relating to the import of drugs

offence	first conviction	Subsequent Conviction
Import of adulterated or spurious drug or spurious cosmetic or any ingredient which may render it unsafe or harmful for use under the directions recommended	Imprisonment upto 3 years & fine upto rupees 5000.00	Imprisonment upto 5 years or fine up to Rs. 10000.00 or Both.
Import of any drug or cosmetic other than referred above, the import of which is prohibited	Imprisonment upto 6 months or fine upto Rs. 500.00 or Both	Imprisonment upto one year or fine upto Rs 1000.00 or Both

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Import of any drug or Cosmetic in contravention of any notification issued under section - 10 A	Imprisonment upto 3 years or fine upto Rs 5000 or Both	add to 3 years Previous.

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Manufacturing of drug

Drug mfg is the process of industrial scale synthesis of pharmaceutical drugs as part of the pharmaceutical industries.

In relation to any drug or cosmetic includes any process of for making, altering or finishing, packaging, labeling, Breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or packaging of any drug in the ordinary course of retail business

* **following licenses are provided for mfg of drug under the drug and cosmetic act and rules their under:**
  - Drugs other than those specified in Schedule - C, C1 & X.
  - Drugs specified in schedule - C, C1 but not specified in schedule - X
  - Drugs specified in schedule - C and C1.
  - Drugs specified in Schedule - X but not in Schedule C and C1.
  - Drug for the purpose of examination, test or analysis.

- Loan licenses
- Repacking licence
- Blood product

* **Prohibition of manufacture and sale of certain drug.**

- Any drug which is not of standard quality or is mis-branded 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 mytigate any disease specified in Schedule - J.
- Any cosmetic containing any ingredient which may render it unsafe or harmful for use.
- Any drug or cosmetic in contravention of this act or rules their under.
- Any drug or cosmetic which has been imported or manufactured in contravention of the provision of this act or rules their under or in contravention of the condition of licence.

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* Manufacture of drugs Specified in Schedule C, C1-X.

Application for the license to mfg drugs Specified in Schedule C & C1 excluding those Specified in Schedule-X should be made to licensing authority in form 27

And for mfg of drugs Specified in Schedule C, C1 & X in form 27B respective licenses are issued in form 28 and 28B

Application for including any additional drug in the licence should be a Competent a fee of Rs 50 for each drug subject to a max. of Rs 500

* Manufacture of drugs Other than those Specified in Schedule C and C1 —

Application for the grant or renewal of a licence for the mfg of drugs Other than those Specified in Schedule C, C1 and X should be made to the licencing authority in form 24 and for mfg of schedule-X drugs in form 24F. The respective licences are issued in form 25 and 25F

* Manufacture of drugs for examination, test, analysis

A licence is nessesary to mfg any drug —

In small quantity for the purpose of examination test or analysis.

* **Manufacture of new drugs** —

No new drug can be mfg unless prior approval of the licencing authority is taken applicant should produced all documentary and other do evidence relating to the standard of quality, purity, strength & such other information as may be required including the results of therapeutic trials carried out on the new drugs.

while applying for a licence to mfg a new drug or its preparation and applicant or should produced along with his application evidence that the drug has already been approved.

* **loan licences** —

loan licences are issued for the mfg. for sale or distribution of drugs other than those specified in Schedule C, C1 and X.

Application for grant or renewal of such loan licences shall be made in form 24A and the licence shall be issued in form 25A.

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* **Repacking licences:-**

Repacking licences are granted for the purpose of breaking up any drug other than those specified in Schedule C and C1 on application to the licencing authority in form 24B and the licence is issued in form 25B

* **Conditions for grant of licence in Schedule C, C1 and X under manufacturing:-**

(i) The mfg will be conducted under the active direction and personal supervision of competent technical staff consisting atleast of one person who is a whole time employ & who is:

(a) a graduate in pharmacy / pharmaceutical chemistry of a recognised university with atleast 18 month practical experience after graduation.

(b) A graduate in science of a recognised University who passed his degree with chemistry or microbiology as a principle subject and had atleast 3 years practical experience in the mfg of drugs to which this licence apply after his graduation.

(c) A graduate in medicine from a recognised University with atleast 3 years experience in the mfg of relevant drug.

A graduate in chemical engineering of a recognised University with atleast 3 years p. experience in the mfg of relevant drugs.

(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 mfg operation as prescribed in schedule M and M_3.

(4) The applicant should make adequate arrangement for the storage of drugs mfg. by him.

(5) The applicant should furnish to the licencing authority 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 G.M.P laid down in schedule M.

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

* **Condition of licence for mfg of drugs for examination, test, 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 mfg and supplied to any person.
- The licencee should maintain and ~~exspection~~ book to enable and to record his impression and defect noticed.
- The licencee must complie with any rule made subsequently and of which the licencing authority has given him not less than one month notice.

Schedule to the rules -

1 * **Schedule - A** :- proforma for application for the licences, issue and renewal of licences for sending memoranda under the act.

* **Schedule - B** :- Rates of fee for test or analysis by the central drug laboratory or gov. analyst.

* **Schedule - C** :- List of biological and special products whose import, sale, distribution and mfg are govern by special provision.

* **Schedule - C1** :- List of other special products whose import, sale distribution and mfg are govern by special provision.

* **Schedule - D** :- List of drugs exempted from the provision of import of drugs.

* Schedule - D :- Information and Undertaking to be submitted by the manufacturer with the application form for a registration certificate.

* Schedule - E :- List of poisonous substances under the Ayurvedic (including Siddha and Unani) System of medicine.

* Schedule - F part 12th/XII B :- Requirement for the functioning and operation of the blood bank or for preparation of blood components.

* Schedule F - part first - A :- provision Applicable to the production of bacterial vaccines.

* Schedule - F - part first - B :- provisions applicable to the production of viral vaccines.

* Schedule - F2 :- Standards for Surgical dressing.

* Schedule - F3 :- Standards for Sterilized umbilical tapes (placenta cut cover tapes) like pregnancy.

* Schedule - FF - Standards for opthalmic preparations.

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* **Schedule - G :-** List of Substances that are required to be used only under medical supervision and which are to be labelled accordingly.

* **Schedule - H :-** List of prescription drugs.

* **Schedule - H1 :-** List of certain antibiotics, anti T.B drugs and Habit forming drugs. not to sold by retail without the prescription of a registered medical practitioner.

* **Schedule - J :-** Disease or ailments which a drug may not purport to prevent or cure.

* **Schedule - K :-** Drugs exempted from certain provisions relating to the mfg. of drugs.

* **Schedule - L1 :-** Good laboratory (G.L.P) practices and requirements of premises / layout and equipments.

* **Schedule - M :-** Good manufacturing practices (G.M.P) - requirements of factory premises plants and equipments.

* **Schedule - M1 :-** Requirements of factory premises etc., Mfg of Homeopathic preparations

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* **Schedule - M2 :-** Requirements of factory premises for the mfg. of cosmetics.

* **Schedule - M3 :-** Requirements of factory premises for mfg. of medical devices.

* **Schedule - N :-** list of minimum equipment for efficient running of a pharmacy.

* **Schedule - O :-** Standards for disinfectant fluid.

* **Schedule - P :-** life period of drugs.

* **Schedule - P1 :-** Pack Size of drugs.

Schedule - Q :- Part One -
list of dyes, colours and pigments permitted in cosmetics and soaps.

Schedule Q. Part Second -
list of colours permitted in Soap.

Schedule - R :- Standards for Condoms made up rubber latex intended for single use and other mechanical contraceptive.

Schedule - R1 :- Standards for medicals devices

Schedule - S :- Standards for cosmetics.

Schedule – T :- G.M.P for Ayurvedic, Siddha and Unani medicine.

Schedule - U :- particulars to be shown in mfg. raw materials and analytical records of drugs.

Schedule – U_1 :- particulars to be shown in mfg. raw materials and analytical record of cosmetics.

Schedule – V :- Standards for patent or proprietary medicine.

Schedule – W- List of drugs which are to be marketed under generic name only.

Schedule X – List of drugs whose import, mfg and sale labelling and packaging are governed by special provision.

Schedule – Y – Requirement and guidlines for permision to import or mfg. of new drugs for sale or to undertake clinical trails.

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Sale of Drugs

Sale is defined as a contract for sale of goods
It's a Contract where by the Seller transfer
or agree to transfer the property in goods
to the buyer for a prisee.

The drugs reach the consumers from the manufacturers by retail through shopkeappers.

Sale of drugs being a specialised job different from the Sale of common goods
the drugs and cosmetic act 1945 and the rules there under provide for a licence for the purpose.

The drug reach the

* Wholesale of Drugs - Wholeseller means a dealer or his agent or stockist engagged in the Sale of drug to a retailer, hospital, dispensary, medical, educational or research institutions or any other agency.

Drugs other than those specified in schedule-C, C1 and schedule - X.

licence issued in form 20-B.
Drug should be purchased only a dully licenced dealer or manufacturer.

Schedule - X Drugs - licence issued in form 20-G.

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Drug Specified in Schedule - C and C1 but not included in to schedule - X

licence issued in form - 20 B

Drugs Specified in Schedule - C and C1 from motor vehicle

licence issued in form - 20 BB

* Retail Sale

General licence (1) | Restricted licence (2)

for retail Sale two type of licenced are issued

1 General licences are granted to persons who have premises for business and who engaged the services of a qualified persons to supervise the Sale of drugs and do the compounding and dispensing.

Conditions -

- licence should be displayed in a prominent place in a part of the premises open to public.
- licences should comply with provision of drugs and cosmetics act and rules thereunder.

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- Any change in the qualified staff incharge should be reported by licencee to licencing authority with in one month

Any change in Constitution of licenced firm should be informed to licencing authority with in 3 month and in the being mean time a fresh licence should be obtained in the name of the firm with changed constitution.

Restricted licences —

licences for restricted sale of drugs other than those specified in schedule - C, C_1 and X and those specified - C, C_1 and — X but not in Schedule - X are issued in form 20A and 21A ~~and~~ respectively.

Condition for restricted licences —

- licences must have adiquet premises equiped with facilites for proper storage of drugs to which licence applies provided that this condition does not applied to vendors.
- licencee should complie with provisions of drugs and cosmetics act and rules inforce.
- Drugs should be purchased only from a duly licenced dealer or manufacturer.

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If licence is a vendor having no fix placed business he should buy drugs from dealers specified in his licence.

- Drugs should sold in there original containers.

prohibition of mfg. and sale of certain drugs.

From the date notified by the State government no person shall himself or any other person on his behalf mfg for sale or for distribution or sale or stock or offer for sale, or distribute:

- Any drug which is not of standard quality or is misbranded, adulterated or spurious.
- Any cosmetics 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 mitigate any disease specified in Schedule - J.

- Any cosmetics containing any ingredient which may render it unsafe or harmful for use.
- Any drug or cosmetics in contravention of this act or rules there under.
- Any drug or cosmetics which have been imported or mfg. in contravention of the provisions of this act or rules there under or are in contravention of the condition of a licence.

Records to be kept in a pharmacy -