

I. Drugs and cosmetics Act, 1940 & Rule 1945-I

- Pharmaceutical Jurisprudence is the study of rules & Regulation of Pharmacy, Pharmacy Practice and also relating to drugs & pharmaceuticals.
- drug & cosmetics act passed - 10 April 1940 & its Rules in 1945. IMP OF 5
- This act is maintain or regulate the import, manufacture, distribution & sale of drug and cosmetics
- This act also verify drugs & cosmetics should be manufactured, distributed & sold only by qualified person having a license for this purpose.

Objectives:-

- for controlling the import of the drug in India, so the substandard or spurious or adulterated drug will enter into country.
- To verify the standards and quality of drugs manufactured in India and regulate their manufacture, sale & distribution.
- controlling the import, manufacturing, distribution & sale of drugs & cosmetics only control or handle by licensing or qualified person.

2. cosmetics :- Any particles intended to be rubbed, poured, sprinkled or sprayed on or introduce into, or otherwise applied on the human body for any part for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes any article intended for use as a component of cosmetics.

3. Misbranded Drugs :-

- if it so coloured, coated, powdered or polished that damage is hidden or if it is made to appear of better or greater therapeutic value than it really is ; or.
- if it is not prescribed manner
labelled
- if it contains a colour which is not prescribed.
- if the label or container or anything accompanying the cosmetics bear any statement which is false or misleading in any particular.

4. Adulterated drugs :- Is deemed to be adulterated

- If it consists, in whole or in part, of any filthy, putrid or decompose substance

injurious or

substance

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6. Patent or Proprietary Medicine :-

- If it has been prepared, packed or stored under unsanitary conditions, so it may have been contaminated.
- If it may have been injurious to health.
- If its contumacy is composed in whole or in part, of any poisonous or deleterious sub. may be injurious to health.
- If it may have been imported under a name which belongs to another drug.
- If it is an imitation of or a substitute for another drug.
- Bears upon its container or label.
- or resembles another drug in likely manner.

5) Similar drug :- If it is imported under a

- or prescription presented in a form ready for internal or external Admin.
- and which is not included in I.P. or others pharmacopeia authorized by their control Govt.

Schedule to Act & Rules :-
Schedule to the Act :-

- It includes any process or part of a process for making, uttering, consuming, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug & cosmetics with a view to its sale or distribution.
- **First schedule :-** This includes the name of Book under Ayurveda, Siddha, Unani & Tibb system.
- **Second schedule :-** This includes the standard to be complied by drugs imported and manufactured for sale, sold, stocked, exhibited for sale or distributed.
- But does not includes compounding or dispensing of any drug.
- or packing of any drug & cosmetics in ordinary course of retail business.

- The following Appendix use also included:-

Appendix - I :- data to be submitted along with the Application for permission to

Market a New drug.

A - II :- format for submission of clinical trials Reports.

III :- requirement for animal clinical trials by Marketing a new drug

IV :- No of animals for long term toxicity study

V :- Patient consent form for participation in phase I clinical trials.

VI :- fair group of fixed dose combinations of their drug cluster requirement.

E) Legal definition of schedules to Rules:-

Schedule :-

A - contains various forms and formats of

Letters for application of licensing etc.,

& sending memorandum.

B - contains fees structure for grant R&D labs.

C - containing various Biological Product

& their regulation import, sell, distribution & Mfg.)

e.g., serums, vitamins etc.,

C) contains others "special products whose regulation use governed by specific provision (Non - purified Administration)

D - list of drugs exempted from the provision of import of drugs.

E - Prescribed list of Poisons substances.

F - Prescribed list of Ayurveda Siddha & Kanni poisons drugs.

G - This contains regulation & standard for Promoting & Blood Bank & Licensing to process the blood components.

H - Prescribes provisions for production of Viaculi Bacterium, vaccines, sera & diagnostic antigen.

I - Standards for surgical dressing.

J - Standards for umbilical sutures.

K - Standards for ophthalmic preparation

M - list of drugs which are required to be taken under the registered medical supervision only.

It labeled with direction schedule or drug, e. curd:-

Dangerous to take this prepn except under medical supervision only.

H.º - List of the drugs that **prescribed** in **Prescription**, Prescription No.

presence of Prescription, Prescription No.

- **Mandatory** for this drug,

- labelled with direction :- to be sold by,

return only on the prescription of
Registered medical practitioner

J.º - **Prescribes** **list** of **Proportion** of
Poisons in certain cases.

J.º - contains list of various disease, or
ailments drugs, or condition that can't
be treated under any drug currently
in market. (No drug may legally claim
to treat these disease)

K.º - **List** of drug **exempted** from the provision
of the manufacture of drugs.

L.º - **Prescribes** classes of drugs which are
exempted from to be sold on **Prescription**
only.

M.º - **Prescribes** good manufacturing practices (GMP)
Requirement of factory premises, plant,
equipment etc., for manufacture of drug.

M.º - requirement of factory premises for Mkt
plant, environment

M.º - Homeopathic Propn
for cosmetics
Medical devices

N.º - contains list of minimum equipment for
efficient running of a pharmancy

O.º - contains regulation regarding standard of
of drug, pack size of drug

P.º - contains regulation regarding life period
of medicines

R.º - contains various regulations of requirement
for condoms & other medicinal
contraceptives.

R.º - standards for medical devices

S.º - standards for cosmetics

T.º - contains various regulation of
equipment for manufacturing of
Ayurvedic, Siddha & Unani products.

U.º - contains various regulation & requirements
for record keeping

V.º - **Prescribes** particular manufacturing areas of
cosmetics

W.º - contains list of drugs to be marketed
under generic names only.

X :- List of drugs whose import, sale, labelling and packaging are governed by specific provision.

Y :- Outlines requirements and guidelines on clinical trials for import and manufacture of new drugs.

Import of drugs :-

- for import of drugs, it is necessary to have a Prior Permission from license authority.
- After filling the registration details regarding drugs to be imported, application for the import license is given by form 5 e.g.
- After verification, license authority issues license by form 10. License is valid for 3 years from date of issue.
- ⇒ conditions for import license :-

1. Any person drug inspectors can collect samples from imported drugs for testing.
2. Importers cannot sell or distribute drugs without permission of licensing authority.
3. Importers has to keep records regarding sale of imported drugs such as to whom it was sold how much & when.

Procedure of import :-

- once you collect the import license of a specific drug, you can conduct the import.

- At the time of import, if the custom collectors has a reason to doubt, he will collect sample from any drug and send it to directors of laboratory appointed for this purpose.

- If the directors of laboratory rejects the drug to be imported is inappropriate and standard then the custom collectors further allow the import.

- If the directors of lab rejects the drug to be imported i.e. belongs to class of drugs prohibited to import, then the custom collectors rejects the import to others export it back to country of origin as the central govt will handle & destroy it within 2 months.
- If the directors of lab rejects that the drug is unacceptable but can be remedied in this case, the custom collector report importers that import will be allowed only if he gives in written that drug will be dispensed only on approved by central govt.

- drugs - prohibited to import :-

- (1) Adulterated drugs
- (2) Misbranded drugs
- (3) Spurious drugs.
- (4) drugs having labelling & packaging in non-prescribed manner
- (5) Drugs of Biological Product after expiry date
- (6) Drugs that do not claim therapeutic value
- (7) Drugs that are harmful to animals & humans.
- (8) Putrid drug whose true formulation is not yet disclosed.
- (9) drugs that claim treatment of Schedule I & II diseases
- (10) Drugs that are prohibited to distribute in the country of origin and use Mf.

- Import under license ~~order~~ Permit :-

- A drug specified in schedule C or C1 only .
- b drug specified in schedule X
- c drug for examination, test or analysis.
- D drug for personal use
- E Any new drug.

M. Drugs specified in schedule C & C1 import:-

- The license for import of schedule C & C1 drugs requires following conditions:
 - license must have adequate facilities for storage.
 - license must maintain the records of sale of drugs, showing particulars of the names of the drugs and of the person to whom they have been sold.
- license must allow an inspector to inspect the premises, where imported drugs are stored and check the record and take the samples for test or analysis.
- license shall supply the sample of drugs from all batches to the licensing authority for test or analysis. (not sell till test)
- license must comply with undertaking given in form no 9.
- The import license may be cancelled or suspended, if condition is not satisfied.

B. drug specified in schedule X - import :-

- A drug specified in schedule C or C1 only .
- b drug specified in schedule X
- c drug for examination, test or analysis.
- D drug for personal use
- E Any new drug.

Required following conditions:-

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Date	

more than 100 doses are imported with license.

- Applying in form NO 12.A & 12.B.

E) Import of New drugs

- License is necessary & license must have adequate facilities for storage.
- The license granted even before should not be suspended or cancelled.
- Applicant must be reputable in the occupation & trade & businesses.
- Import of small quantities of drug for examination, test or analysis.
- Requires following conditions:-

- drugs exempted from provision regulating imports of drug :-

- The licensee must return the records of imported drugs, showing particulars of their quantities, names of manufacturer & date of import.
- Imported under license in form II.

D. Import of drugs for personal use:-

Required following conditions:-

- The drug must be Bonafide personal use.
- The quantity should be reasonable and covered by B.M.P. prescription.
↳ Registered Medical Practitioner
- The drug shall be declared to the customs authority. It thus, clear so,

Some important forms for imports of drugs

form 8 :- Application for licence to import

Schedule C & C drugs only.

5A :- Application for Licence to Import drug

Specified in Schedule X

form 9 :- form of undertaking to accompany an application for an import licence

form 10 :- Licence to import schedule C & C drugs only

10 A :- Licence to import schedule A drug only

- form 41 :- Registration certificate to be issued for import of drugs in India.
- * Both the import license & registration certificate are valid for a period of 3 yrs.
- from date of issue.

Offences & Penalty Related to Import of Drugs

Offences	Penalty	Jail	Conditions
Import of adulterated, spurious or cosmetic unsuitable for use	up to 5000 up to 10000 up to 50000	up to 3 yrs on first conviction. up to 5 yrs on 2nd conviction.	
Import of any drugs or substances other than import which is prohibited	up to 500 up to 1000 upto 1428	up to 6 m. 2nd conviction	

import of any drugs or cosmetics in contravention of provision of section 10-A	up to 5000 up to 10000	upto 2 yrs 2nd conviction	1st conviction
no application issued under section 10-A	5 yrs	conviction	

Manufacturing of drugs :- general drugs -

- manufacturing of drug Refers to drug process of marking, altering, finishing, ornamenting, labelling, packaging of drug But doesn't involve dispensing & retail business of drug.

Procedure :-

- Before manufacturing of drug license for drug manufacturer is required.
- Application in form 24 is given along with documented evidences regarding purity & quality of drug for manufacturing license.

- After verification, the license authority issue license in form No. 25.

conditions of manufacturing license :-

- The factory premises should fulfill all the conditions mentioned on schedule N.
- Disney inspectors can inspect the premises anytime and check records & samples of drugs.
- Inspection book should be maintained.
- Records should be kept regarding manufacture of drugs, In case expiry date comes, record should be maintained for 2 yrs after expiry.
- Reference sample should be collected for every batch of manufacture, and its quantity should be such that all tests can be performed twice.
- Any changes in factory or staff members should be reported to the Authority.
- The manufacturing should always be under supervision of competent staff members.
- There should be a sufficient storage space for manufacturing drugs & an appropriate testing unit separated from manufacturing unit.
- License must be displayed on the premises.

Prohibition of Manufacturing & sale of certain drugs:-

- 1) Any drugs or cosmetics which is substituted, misbranded, adulterated or spurious.
- 2) Any Patent or Proprietary Medicine.
- 3) Any drug claiming for cure of disease listed in Schedule I.

- 4) Manufacturing for sale of any drugs or cosmetics containing any harmful ingredient.
- 5) Any Manufacturing of formulation containing drug or cosmetic which has been imposed into our country in contravention to the provision of the acts & rules.

Manufacture of drugs for test, examination & analysis :-

- Required following conditions:-
- 6) The license is obtained from licensing authority by form No. 29.

- Licensee must use manufactured drugs exclusively for purpose for which they are manufactured
 - Must maintain the records of the manufacture of drugs, showing their quantity & name of the persons to whom they have been supplied.
 - Maintenance Inspection Book
 - Licensee must comply with such additional requirements of which he has been given at least 1 month notice by the license authority
- ⇒ other same as general conditions.

Manufacture of drug scheduled C, C₁

- drugs scheduled C, C₁ are biological drugs
- Application for manufacturing license is given us form no. 25
- After verification license is issued by Authority As form no 29
- Conditions:- (for licensee)
 - 1. The customers should be of firms & centralized to fill the manufactured product.
 - 2. The drugs should follow the standards of Schedule F.
 - 3. Some classes of Biological drugs need to be tested for micro-organism presence.
e.g. J. Insulin, B.C. Vaccine.
 - 4. Serum need to be tested for abnormal activity.
 - 5. Pharmaceutical Administration drugs need to be tested for presence of pyrogens.
 - 6) The factory must have separate lab unit for culturing of pathogens.
 - (7) If the drug is being formulated for animals it's must be supervised by a veterinary graduate.
 - (8) Write general conditions:

Manufacturing of schedule X drugs.

- Nuncotic & Psychotropic drugs Belong to schedule X

- Application for license is given by form 27-B
- Application for classification license is issued as
- After classification license is given by form 28-B.

Conditions (for license)

- An invoice of drug manufactured e.g. An amount of scale should be sent to Authority every 3 months.
- This drug cannot be given to physicians as samples.
- They are labelled as T.P.Y or N.P.Y with Red ink
- Their formulation does not exceed centring limit of dosage, e.g. 300 mg → oral liquid 6 ml → injection.
- (2) A drug that is modified from preservative approved drug i.e., changing its dose, dosage form, route of administration, indication etc.,
- (3) A formulation drug made by mixing 2 or more previously approved drug in a fixed ratio, it will have new dose, dosage form, indication & better effects.
- (4) A drug is combined to be new, until 4 years of its first approval for license is given by form 44
- It is necessary to submit data that proves its efficacy & safety along with application.
- also the results of clinical trial conducted as per schedule 4 need to be submitted.
- A new drug can be considered as
 - (A) A drug that is not being used in the country till now & whose safety & efficacy is not approved by licensing authority,
 - same as general drugs manufacturing

Manufacturing of New drug

Lawn Licenses

Manufacturing under lawn licenses :-

- "lawn licenses" \Rightarrow Applicant does not have own manufacturing unit, but wishes to use manufacturing unit of others. Licenses issued are called as lawn licenses.

- lawn license for manufacturing of schedule X drugs is not issued.

- Application is given by form 24-A & license is issued after verification by form 25-A

conditions:-

- (1) Application must be supported by parent firm \Rightarrow It should be supervised by competent staff members.
- (2) If the license of parent firm is suspended or cancelled, lawn license will also be suspended or cancelled.
- (3) during inspection would inspect the premises whether it is sufficient for another production or not.
- (4) write common conditions

Repacking license

- Breaking of drugs from its bulk container to small packages for purpose of distribution by sale is repacking and this process also requires license.
- Repacking license for drugs scheduled C, C, I $\&$ is not granted.

- Application is given by form 24-B to the Authority of license is issued by form 25-B.

conditions:-

- Repacking should be done in hygienic conditions
- Analysis of packed & repacked drugs is done and the records are maintained
- drug inspectors can take samples of repacked drugs for testing.
- The repacked drug should have a label of RPL license no... .
- other common conditions related to factory.