
**JES's college of Pharmacy,Nandurbar**

# Drug and cosmetics Act,1940 and its rules 1945

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# IMPORT of drugs

Classes of drugs prohibited to import

- Import of drug under license

1) Specified in Schedule-C/C1
2) Specified in Schedule-X
3) Imported for Test/Analysis
4) Imported for personal use
5) Any new drugs

• Drugs exempted from provisions of import

• Offences and Penalties

# Classes of drugs prohibited to import

- Misbranded drugs
- Drugs of substandard quality
- Drugs claiming to cure diseases specified in Sch-J
- Adulterated drugs
- Spurious drugs
- Drugs whose manufacture, sale/distribution are prohibited in original country, except for the purpose of test, examination and analysis.
- Patent/Proprietary medicines whose true formula is not disclosed.

# Import of the biological drugs(C/C1)

Conditions to be fulfilled:

- Licensee must have adequate facility for the storage.
- Licensee must maintain a record of the sale.
- Licensee must allow an inspector to inspect premises and to check the records.
- Licensee must furnish the sample to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and recall the batch from the market.

# Import of the Schedule-X drugs (Narcotic & Psychotropic drugs)

Conditions to be fulfilled:

- Licensee must have adequate storage facility.
- Applicant must be reputable in the occupation, trade or business.
- The license granted even before should not be suspended or cancelled.
- The licensee has not been convicted any offence under the Drugs and Cosmetics Act or Narcotic and Psychotropic Substances Act.

# Drugs Imported for examination, test or analysis

Conditions to be fulfilled:

- License is necessary under form-11
- Must use imported drugs only for said purpose and at the place specified in the license.
- Must keep the record with respect to quantities, name of the manufacturer and date of import.
- Must allow an inspector to inspect the premises and check the records.

# Drugs imported for personal use

Conditions to be fulfilled:

- Up to 100 average doses may be imported without any permit, provided it is part of passenger's luggage.
- More than 100 doses imported with license. Apply on form no.-12-A,12-B
- Drugs must be bonafide personal use.
- Drugs must be declared to the custom collectors if so directed.

# Import of drugs without license

- Substances which are both drugs and foods such as: Condensed/Powdered Milk, Malt
- Substances not used for medicinal purpose Lactose, Farex/Cereal, Oats, Predigested foods, Ginger, Pepper, Cumin, Cinnamon

# Penalties related to Import

| OFFENCES | PENALTIES |
| --- | --- |
| Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values | a) 3 years imprisonment and 5000 Rs. fine on first conviction<br>b) 5 years imprisonment OR 1000 Rs. fine OR both for subsequent conviction |
| Contravention of the provision | a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction<br>b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence |

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# Cosmetics prohibited to import

- Misbranded cosmetics
- Spurious cosmetics
- Cosmetic containing harmful ingredients
- Cosmetics not of standard quality which contains more than- 2 ppm Arsenic, 20 ppm lead, 100 ppm heavy metals

# MANUFACTURE

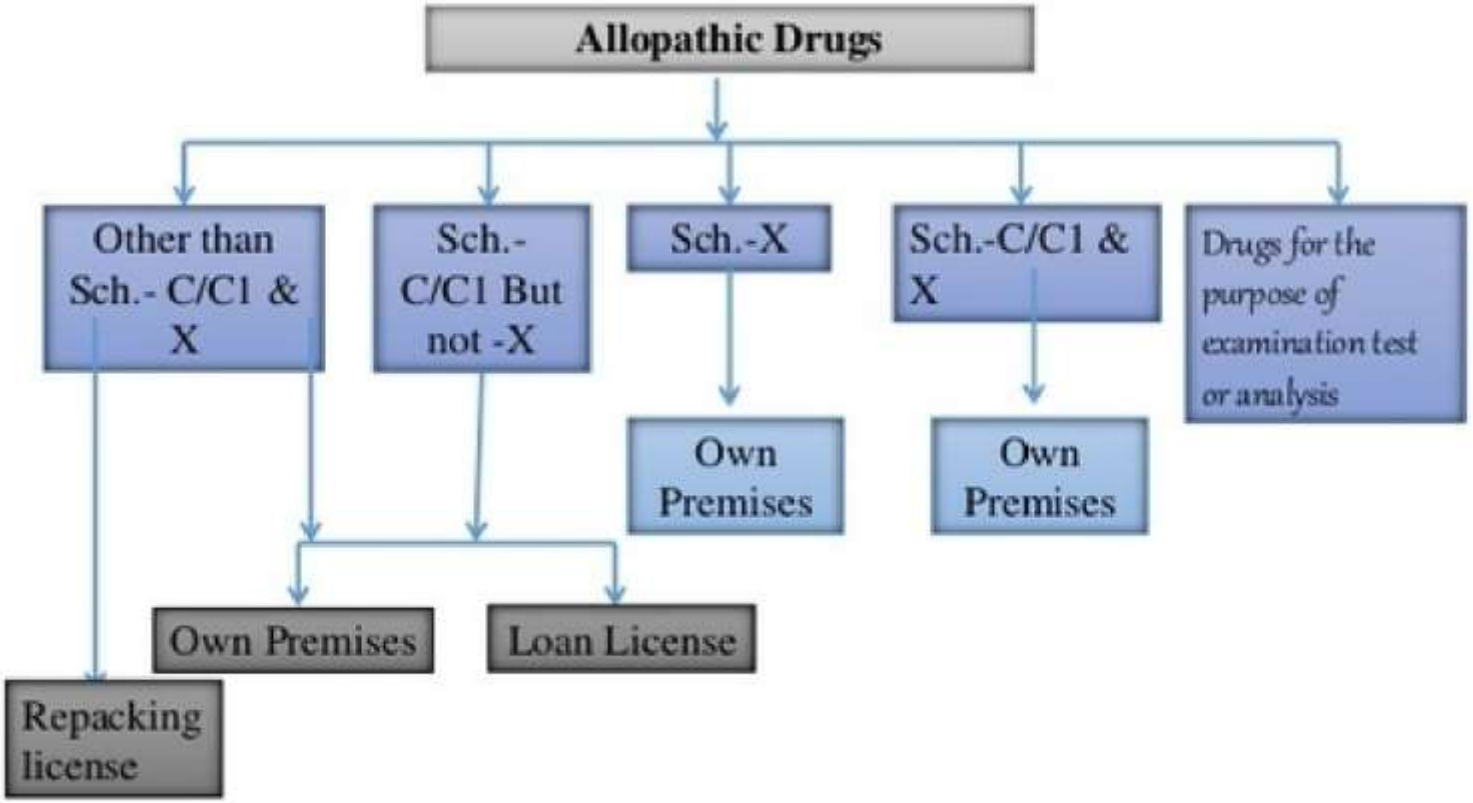
Prohibition of manufacture

- Manufacture of other than in Sch-C/C1
- Manufacture of those in Sch-C/C1
- Manufacture of Sch-X drugs
- Loan license
- Repackaging license
- Offences & Penalties

# Prohibition of manufacture

- Drug not of standard quality or misbranded, adulterated or spurious.
- Patent or Proprietary medicine or drugs in Sch-J
- Risky to human beings or animals
- Drugs without therapeutic value
- Preparation containing cyclamates

# Types of manufacturing license



# Manufacture of drugs other than in Schedule- C/C1 Conditions:

- Premises should comply with schedule ‘M’
- Adequate facility for testing, separate from manufacturing
- Adequate storage facility
- Records maintained for at least 2 years from date of Exp.
- Should provide sample to authority
- Furnish data of stability
- Maintain the inspection book
- Maintain reference samples from each batch

## FORM 24

[*See* Rule 69]

*Application for the grant of or renewal of a licence to manufacture for sale* [87][*or for distribution of*] *drugs other than those specified in* [88][*Schedules C, C(1) and X*]

1. I/We . . . . . of . . . . . hereby apply for the grant/renewal of a licence to manufacture on the premises situated at . . . . . the following drugs being drugs other than those specified in [88][Schedules C, C(1) and X] to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs categorised according to Schedule M.

3. Names, qualifications and experience of technical staff employed for manufacture and testing.

4. A fee of rupees . . . . . has been credited to Government under the head of account . . . . . .

*Date* . . . . . *Signature* . . . . . .

Note.—The application should be accompanied by a plan of the premises.

# Manuf. of drugs those in Schedule-C/C1(Biological)

Conditions:

- Drugs must be issued in previously sterilized sealed glass or suitable container
- Containers should comply with Sch-F
- Some classes tested for aerobic & anaerobic microorganism. eg. Sera ,Insulin, Pituitary hormones.
- Serum tested for abnormal toxicity
- Parenteral in doses of 10 ml or more should be tested for freedom from Pyrogens
- Separate lab. for culture & manipulation of spore bearing Pathogens
- Test for sterility should be carried out.

# Manufacture Of Sch-X drugs

Conditions:

- Accounts of all transactions regarding manuf. Should be maintained in serially.(Preserved for 5 years)
- Have to sent invoice of sale to licensing authority every 3 months
- Store drugs in direct custody of responsible person.
- Preparation must be labeled with X-Rx
- Marketed in packing not exceeding
- 100 unit dose –Tablets/Capsules
- 300 ml- Oral liquid
- 5 ml - Injection

# Manufacture of cosmetics

Prohibited for the following classes of drug:

- Misbranded or spurious cosmetics and of substandard quality
- Cosmetics containing hexachlorophene or mercury compounds
- Cosmetics containing color which contain more than-
- 2 ppm of arsenic
- 20 ppm of lead
- 100 ppm of heavy metals
- Eye preparations containing coal-tar color

# Penalties related to Manufacture

| OFFENCES | PENALTIES |
|---|---|
| Manufacture of any spurious drugs | a) 1-3 years imprisonment and Rs.5000 fine<br>b) 2-6 years imprisonment & Rs.10000 fine on subsequent conviction |
| Manufacture of adulterated drugs | a) 1 year imprisonment & Rs.2000 fine<br>b) 2 years imprisonment & Rs.2000 fine for subsequent conviction |
| Manuf. of drugs in contravention of the provisions | a) Imprisonment up to 3 months & Rs.500 fine<br>b) Imprisonment up to 6 months & Rs.1000 fine on subsequent conviction |

# Loan License

Definition:

- A person(applicant) who does not have his own arrangements(factory) for manufacture but who wish to manufacturing facilities owned by another licensee such licenses are called Loan licenses.
- Loan licenses are issued for:

1) Drugs other than specified in C/C1 & X.

2) Drugs specified in Schedule-C/C1

# Repackaging license

Definition:

- Process of breaking up any drug from a bulk container into small packages and labelling with a view to their sale and distribution.
- Repackaging of drugs is granted of drugs other than Schedule-C/C1 and X

# SALE

Classes of drugs prohibited to be sold

- Wholesale of biological (C/C1)
- Wholesale of other than those specified in C/C1 and X

# Class of drug prohibited to sale

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/Proprietary drugs with undisclosed formula
- Sch-J drugs
- Expired drugs.
- Drugs used for consumption by government schemes such as, Armed force.
- Physician’s samples

# Wholesale of biological (C/C1)

- Adequate premises, with greater than 10 M2 area, with proper storage facility
- Drugs sold only to retailer having license
- Premises should be in charge of competent person who is Reg. Pharmacist.
- Records of purchase & sale
- Records preserved for 3 years from date of sale
- License should displayed on premises

# whole sale from other than specified in C/C1 and X

- All the conditions as discussed in for biological. Compounding is made by or under the direct and personal supervision of a qualified person.

# Sale of Drugs

- Sale may be defined as the process of passage of articles from the manufacturer to the consumer.
- There are two general types of sale
  - Retail sale
  - Wholesale
- **Retail Sale:** It means a sale whether to a hospital or a dispensary or medical, educational, or research institute or to any other person other than a sale by way of wholesale dealing.
- **Wholesale:** (sale by way of wholesale dealing) It means a sale to a person for the purpose of selling again & also includes a sale to hospital or a dispensary or medical, educational, or research institute

- **Drug store:** It means a licensed premises for the sale of drug who do not require the services of a qualified person.

- **Chemist & druggist:** It means a licensed premises for the sale of drug who requires the services of a qualified person but where the drugs are not compounded against prescription.

- **Pharmacy:** It means a licensed premises for the sale of drug who requires the services of a qualified person but where the drugs are compounded against prescription.

# Form no. in which licenses are issued for the sale, stock, exhibit for sale or distribution of drugs

| License issued | Form No. | | |
|---|---|---|---|
| | Drugs other than Sch.C,C1 & X | Sch. C&C1 drugs | Sch.X drugs |
| Retail | 20 | 21 | 20-F |
| Restricted | 20-A | 21-A | - |
| Wholesale | 20-B | 21-B | 20-G |
| Wholesale or distribution from motor vehicle | 20-BB | 21-BB | - |

# Kinds of licenses for wholesale

# Kinds of licenses for Retail sale

# Wholesale of schedule C&C1 drugs

- Following conditions are to be satisfied by the licensee having wholesale of schedule C&C1 drugs
- The license should be displaced in a prominent part of premises opened to the public.
- The licensee must have adequate premises which should not be less than 10 sq. meters, equipped with facilities for the proper storage of drugs.
- Licensee should maintain records related to all purchase & sale of drugs, with particular such as

  a) date of purchase & sale

  b) name & addresses of the person from whom purchased & to whom sold.

  c) names & quantities of drugs & their batch no.

  d) names of manufacturers of drugs
- Drug should be purchased from dully signed manufacturer.
- Drug should be sold only to those persons who are licensed to retail them.
- The licensee should comply with all the provisions as per the act.

## Wholesale of drugs other than those specified in schedule C&C1

- Drugs should not be sold to any person who do not hold the license for the retail sale or distribution of drugs of these class.
- The general conditions as mentioned in previous slide

## Wholesale from motor vehicle

- The general conditions as mentioned in previous slide
- Separate license is necessary for schedule C&C1 drugs & other than those specified in schedule C&C1
- The license should be displaced in the prominent place in the vehicle.
- Drugs may also be distributed to govt. hospital or institutions.

## Retail sale from shops

- Facilities as per schedule N.
- Purchased only from licensed wholesalers.
- No sale of specified drugs
- Separate license for sch. C,C1 & X drugs.
- Sale under qualified supervision.
- Records
- Inspection
- Sale of specified households drugs from drug stores.

# Licenses for chemist & druggist shops & pharmacy

- The license granted subject to the following conditions.
- The licensee must have adequate premises & facilities for proper storage of drugs & under the supervision of competent person for sale & distribution of drugs.
- Must fulfill the requirements as per sch. N.
- Must obtain the permission to sale additional categories of drugs.
- Licensee must maintain records of drugs.
- Licensee must allow an inspector to inspect the premises & to check the records.
- Licensee must inform to the licensing authority about any change in qualified staff.
- Precaution must be taken during storage of sch C & C1 drugs.

# Sale of Sch. H & X drugs

- Drugs specified in schedule H & X should be sold only on prescription of RMP.
- In case of sch. X drugs, the prescription should be in duplicate & should be retained for 2 years.
- The cash or credit bill should bear a signature of customer with his address.
- Separate bound & paged registers should be maintained for supply in which separate sheets should be allotted for each drug.
- The following particulars should be enter at the time of supply

a) date of supply

b) opening & closing stocks of drugs on that day & relevant bill number.

c) name of the drug, its manufacturers name & batch no.

d) name & address of the purchaser

e) date of prescription & name & address of RMP

f) signature of Registered pharmacist under whose supervision supply is made.

- Supply of drugs to medical practioner & other institution should be preserve for at least 3 years from the date of supply.

- General license: general license is granted to a person who have premises for business & who have engage the services of qualified person to supervise the sale of drug & do the compounding & dispensing.

- Restricted license: restricted license is granted to those dealer who do not engage the services of qualified person.

# Classes of drugs prohibited for wholesale

- Misbranded, spurious & adulterated drugs & drugs not of standard quality
- Any patent or proprietary medicine
- Any drug which claims to cure or prevent any disease or ailments as described in sch J.
- Any drug manufactured or imported in contravention to the act.
- Drugs whose date of expiry has expired.
- Drugs intended for supply to central govt. health scheme or govt hospital or institution.
- Physician samples.
- Drugs not intended for sale.

# Offenses & penalty for sale of drugs

Sale, stocking, exhibition or offer for sale of drugs likely to cause death or grievous hurt as per sec. 320

- 5 years----life imprisonment & not less than Rs. 10,000 fine.

Sale, stocking, exhibition or offer for sale of adulterated drug

- 1-3 years imprisonment & not less than Rs. 5,000 fine on first conviction & 2-6years imprisonment & not less than Rs. 10,000 fine on subsequent conviction

Sale, stocking, exhibition or offer for sale of spurious drugs

- 3-5 years imprisonment & not less than Rs. 5,000 fine on first conviction & 6-10 years imprisonment & not less than Rs. 10,000 fine on subsequent conviction

Sale of drug in contravention of any other provision

- 1-2 years imprisonment & fine on first conviction & 2-4 years imprisonment & not less than Rs. 5,000 fine on subsequent conviction

Failure to keep records or disclosed required information

- Imprisonment upto 1 year & or fine upto Rs. 1000

False warranty to purchaser

- Imprisonment upto 1 year & or fine upto Rs. 5000 on first conviction & 2 years imprisonment or fine or both on subsequent conviction.

Use of govt. analyst report or CDL report for advertising

- Fine upto Rs.500 on first conviction & imprisonment upto 10 years or fine or both on subsequent conviction.

# Labeling


NDC 51672-4028-3
1000 Tablets
Warfarin Sodium
Tablets, USP Crystalline
2 mg
PROTECT FROM LIGHT.
HIGHLY POTENT ANTICOAGULANT.
WARNING: Serious bleeding results from overdosage. Do not use or dispense before reading directions and warnings in accompanying product information.
Rx only
TARO
Usual adult dosage: Read accompanying product information.
Store at 20-25C (68-77F) [see USP Controlled Room Temperature].
Dispense in a tight, light-resistant container as defined in the USP.
RESEAL CAP TIGHTLY.
Mfd. by:
Taro Pharmaceutical Industries Ltd.
Haifa Bay, Israel 26110
Dist. by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.

# Labeling & Packing of drug as per D&C Act 1940

Legal requirements for labeling of drugs are as follows

- Name of drug (official name, trade name)
- Name of manufacturer & his address along with license no. & batch no.
- Potency, standard, grade, dose etc expressed as ML, grains, units etc.
- Net contents by volume/weight/number
- Manufacturing & expiry dates (schedule P & C drugs only)
- Precautions for handling, storage, sale or usage etc.
- Special instructions may be there such as for veterinary use, physician sample etc.
- Special labeling for, “drug for export”, “dispensed drug”.

## For schedule G drugs

- "Caution: It is dangerous to take this preparation except under the medical supervision".

## For schedule H drugs

- Warning: To be sold by retail on the prescription of a registered medical practitioner only".
- Symbol Rx prominently on left hand top corner of the label.
- Symbol NRx prominently on left hand top corner for narcotic & psychotropic substances.

## Schedule X drugs

- "schedule X drug Warning: To be sold on prescription of RMP only.
- Symbol XRx in red on left hand top corner.

## Ophthalmic solution/suspension/ointment


- Use within one month after opening the contain
- FOR OPTHALMIC USE ONLY
- NOT FOR INJECTION
- Name & concentration of preservatives if used.
- Special instructions regarding storage wherever applicable.
- Warning: If irritation persist or increases, discontinue the use & consult the physician.
- Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate the solutions.

# Veterinary drugs

- Not for human use
- For animal treatment only
- Head of any domestic animal


## Packing of drugs specified in Sch X

- The drugs specified in sch. X can be marketed in packing not exceeding

i) 100 unit doses in case of tablet/capsules

ii) 300 ml in case of liquid preparation

iii) 5 ml in case of injection.

- For 10 ml vial of insulin 80 units/c.c.

Rx INSULIN

80 units/c.c.

Schedule G drug

Caution: It is dangerous to take this preparation except under medical supervision only

Mfg lic no.A-320

Batch No. B-111

Mfg date: April 2009

SaeE Pharmaceuticals Ltd.

D-99 MIDC, Butibori, Nagpur

# Labeling of cosmetics

1. On both inner & outer label it should indicate
   - Name of the cosmetic
   - The name & address of the manufacturer
2. On the outer label, it should indicate the net content of the package. Such statement need not appear on the label if the net content does not exceeds 60 ml/30 grams
3. On the inner label, it should indicate, the proper direction of safe use, warning, caution, or the 'special direction' & the names & contents of ingredients that are poisons or hazardous.
4. The label in addition should indicate
   - batch no., only if the content of cosmetics is more than 10 gms or 25 ml, in case of soap instead of batch no. the month & year of manufacture of soap shall be given on the label.
   - Mfg lic no. Preceded by letter M.
5. If the package or container of the cosmetic has only one label, it should contain all the information required to be shown on both inner & outer label.


Cosmedics
Cosmedics
Cosmedics
Cosmedics
Cosmedics
Cosmedics

## Labeling of hair dyes

- Hair dyes containing coal tar color should label (inner & outer)
- “Caution: This product contains ingredients which may cause skin irritation in certain cases & so a preliminary test according to directions should first be made . The product should not be used for dyeing eye lashes or eye brows, as such as use may cause blindeness.

# Hair Dye Label Sample

# Labeling of toothpaste containing fluorides

- Fluoride content in tooth paste shall not be more than 1000 ppm & the content of fluoride in terms of ppm shall be mentioned on tube & carton
- Date of expiry shall be mentioned on tube & carton

# List of Permitted Colors

(viii) Proprietary name,

proprietary name).

**LIST OF COLOURS PERMITTED TO BE USED IN DRUGS : (UNDER RULE 127)**

Following colours may be permitted to be used in medicines. The label on the container of drug containng a permitted colour shall indicate the common name of the colour.

1. **Natural colours :** Annatto, carotene chlorophyll, cochineal, curcumin, Red oxide iron, Yellow oxide or iron, titanum oxide, black oxide of iron.

2. **Artifical colours :**

   1. Caramel.

   2. Riboflavine.

# List of Permitted Colors



**3. Coal Tar Colours :**

| Common name of the colour | Colour Index Number |
|---|---|
| **Green** | |
| Quinazarine Green SS | 61565 |
| Alzarin Cyanine Green F | 61570 |
| Fast Green FCF | 42053 |
| Green S | 44090 |
| **Yellow** | |
| Tartazine | 19140 |
| Sunset yellow FCF | 15985 |
| Quinoline Yellow WS | 47005 |
| **Red** | |
| Amarnath | 16185 |
| Erythrosine | 45430 |
| Eosin YS or Eosin G | 45380 |
| Tony Red or Sudam III | 26100 |
| Ponceau 4 R | 16255 |
| Carmosine | 14720 |
| Fast Red E | 16045 |

# List of Permitted Colors

| | |
|---|---|
| Blue | |
| Indigo Carmine | 73015 |
| Brilliant Blue FCF | 42090 |
| Orange | |
| Orange G | 16230 |
| Brown | |
| Resorcin Brown | 20170 |
| Black | |
| Napthol Blue Black | 20470 |

4. **Lakes :** The aluminium or calcium salts (lakes) of any of the water soluble listed above.

# Thank you