Name of Unit	Drugs and Cosmetics Act, 1940
Subject /Course name	Pharmaceutical Jurisprudence
Subject/Course ID	BP 505T
Class: B.Pharm. Semester	5
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Learning Outcome of Module 02

LO	Learning Outcome (LO)	Course Outcome Code
LO1	We learnt about Study of Schedules G, H, M, N, P, T, U, V, X, Y.	BP505.3
LO2	We learnt about Sale of Drugs in Wholesale, Retailer and Restricted License.	BP505.3
LO3	General Labeling Requirements of Drugs and Packing of Drugs.	BP505.3
LO4	Drug Technical Advisory Board	BP505.3
LO5	Drug Consultative Committee	BP505.3

Content Table

Topic
• Study of Schedules G, H, M, N, P, T, U, V, X, Y • Sale of Drugs in Wholesale, Retailer and Restricted License. • General Labeling Requirements of Drugs • Packing of Drugs • Drug Technical Advisory Board • Drug Consultative Committee

Drugs and Cosmetics (Amendment) Act, 2008

Salient features of the Act:-

- Substantial **enhancement in punishment**
- **Life imprisonment** for offenders involved in manufacture, sale and distribution of spurious and adulterated druglikely to cause **grievous hurt**
- **Minimum** punishment of **seven years** which may extend to life imprisonment
- Provision for compensation to affected person

Drugs Manufacturing License

- Own License (Form)
  - Drugs (25 & 28)
  - Cosmetics (32)
  - Homeopathic (25C)
  - Ayurvedic (25D)
  - Blood Bank (28C)
- **Loan License (Form)**
  - Drugs (25A & 28A)
  - Cosmetics (32A)
  - Ayurvedic (25E)
- **Allopathic License (25, 28, 28C)**

Condition of License

- Premises
- Technical Staff
- Plant & Machinery
- Documents

- **Trading License**

Allopathic

Retailer – Form 20, 21 & 20C

(Homeopathic) Wholesaler – Form 20B, 21B & 20D (Homo.)Note –

No trading license for sale of Ayurvedic Drugs as per Drugs & Cosmetics Act.No trading license required for sale of cosmetics.

Documents

- Requisite Drugs Trading License
  - Premises/ ownership document of premises
  - Pharmacist or Competent person.
  - Partnership deed/Memorandum of Article etc
  - Pharmacist appointment & acceptance letter
  - Refrigerator purchase receipt

Administration of the act and rules

A) Advisory :

1) Drugs Technical Advisory Board-DTAB 2) Drugs Consultative Committee-D.C.C.

B) Analytical :

1) Central Drugs Laboratory - CDL 2) Drug Control Laboratory in states 3) Government Analysts

C) Executives:

1) Licensing authorities
2) Controlling authorities
3) Drug Inspectors

Drugs Technical Advisory Board (DTAB)

Ex-Officio Members:

(i) Director General of Health Services (Chairman)

(ii) Drugs Controller, India

(iii) Director of the Central Drugs Laboratory, Calcutta

(iv) Director of the Central Research Institute, Kasauli

(v) Director of Indian Veterinary Research Institute, Izatnagar

(vi) President of Medical Council of India

(vii) President of the Pharmacy Council of India

(viii) Director of Central Drug Research Institute, Lucknow

(viii) Nominated Members:

1) Two persons by the Central Government.
2) One person by the Central Government from the pharmaceutical industry
3) Two persons holding the appointment of Government Analyst under this Act

Elected Members:

1) One person, to be elected by the Executive Committee of the Pharmacy Council of India,
2) One person, to be elected by the Executive Committee of the Medical Council of India,
3) One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;
4) One person to be elected by the Central Council of the Indian Medical Association;
5) One person to be elected by the Council of the Indian Pharmaceutical Association;

Functions:

- To **advise** the Central Government and the State Governments on technical matters
- To carry out the other functions assigned to it by this Act

Drugs Consultative Committee (DCC)

It is also an **advisory body** constituted by central government.Constitution:

Two representatives of the **Central Government**

One representative of each **State Government**

Functions:

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any othermatter tending to secure **uniformity throughout India** in the administration of this Act
- The Drugs Consultative Committee shall **meet when required**
- Has power to regulate its own procedure

Central Drug Laboratory (CDL)

Established in **Calcutta**, under the control of a director appointed by the Central Government.

Functions:

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts
- Analytical **Q.C.** of the imported samples
- Collection, storage and distribution of **internal standards**
- Preparation of **reference standards** and their maintenance
- Maintenance of **microbial cultures**
- **Any other duties** entrusted by Central Government

- Acting as an **appellate authority** in matter of disputes

The Central Drugs Laboratory

- Provides for the establishment of a Central Drugs Laboratory under the control of a director appointed byCentral Government

The Laboratory established in Calcutta has been entrusted with the following functions

1) to analyze or test samples of drugs or cosmetics sent to it by the cosmetics collectors or courts

2) to carry out such other duties entrusted to it by the Central Government or with its permission, by StateGovernments, after consultation with DTAB

- The Central Research Institute, Kasauli carries out functions in respect of sera, solutions of serum, proteins forinjections, vaccines, toxins, antigens, antitoxins, sterilized surgical ligatures and sutures and Bacteriophages
- Vetenary Research Institute, Izantnagar and Mukteshwar carries out functions in respect of antisera, vaccines,toxoids & diagnostic antigens, all for Vetenary Use

Drug Control Laboratories in State

In Karnataka three laboratories established which collect, analyze and report the various sample of the drugs and foodThe laboratory has the following divisions:-

- Pharmaceutical Chemistry Division
- Pharmacology Division
- Pharmacognosy Division
- Food Division
- Ayurvedic Division

Functions:

- Testing of drug sample
- Analysis of food sample
- Analysis of excise sample

Government analyst

These officers are appointed by the central or state government and perform the duties

- State Government by notification in the Official Gazette, appoint persons having sufficient qualifications to be government Analysts for such areas in state & in respect of such drugs and classes
- Central Government may also similarly appoint Government Analysts in respect of such drugs or

classes of drugsor cosmetics as specified

- No person having any interest in the import, manufacture or sale of drugs or cosmetics or is directly or indirectlyengaged in any trade or business connected with manufacture of drugs can be appointed as Government analysts

Qualifications

- A graduate in medicine/science/pharmacy/pharmaceutical chemistry of recognized University and have 5 yrs post graduate experience in testing of drugs in a laboratory under the control of 1)a Government Analyst or 2)head of approved Institution or testing laboratory.
- A Post Graduate in medicine/science/pharmacy/pharmaceutical chemistry of recognized University with at least 3 years of experience in the testing of drugs in a laboratory under the control of 1)a Government Analyst or 2) head of approved Institution or testing laboratory.

Duties of Government Analyst

- Analyze or test samples of drugs/cosmetics sent to him by inspectors or other persons under the act and tofurnish reports of the results of test or analysis.
- Forward to Government from time to time, reports giving the results of analysis works and research with a viewto their publication at the discretion of Government.

Procedure

- On receipt of package of sample from an Inspector the Government Analyst should compare the seals on thepackage with the specimen seals and note its condition. On completion of test, reports in triplicate together with full protocols of the tests or analysis should be sent to the Investigator.
- Government Analyst has to submit a report in form 1 and unless full protocols are supplied, the report cannot beregarded as conclusive evidence.

Licensing authority

Qualification:

- (i) Graduate in Pharmacy on Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a University established in India by law; and
- (ii)Experience in the manufacture or testing of drugs a minimum period of five years, Provided that the requirements as to the academic qualification shall not apply to those inspectors

Duties:

- (1) to inspect all establishments licensed for the sale of drugs within the area assigned to him;

- (2) to satisfy himself that the conditions of the licenses are being observed;
- (3) to procure and send for test or analysis, if necessary, imported packages.
- (4) to investigate any complaint.
- *(5) to maintain a record of all inspections made and action taken by him in the* performance of his duties,
- *(6) to make such enquiries and inspections as may be necessary to detect the sale of* drugs in contravention tothe Act;

Controlling authority Qualification:

Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical Pharmacology or microbiology from a University established in India by law and experience in the manufacture or testing of drugs orenforcement of the provisions of the Act for a minimum period of five years

Schedule DII

Information required to be submitted by the manufacturer or his authorized agent with the Application Form for the registration of a bulk drug/formulation/special product for its import into India. The format shall be properly filled inand, may be furnished on a Computer Floppy.

General requirement

1.1 Name of the drug/formulation/special product, a brief description and the therapeutic class to which it belongs.

1.2 Regulatory status of the drug. Free Sale Certificate and/ or Certificate of Pharmaceutical Products (CPP) issued bythe Regulatory Authority of the country of origin.

1.3 Drugs Mater File (DMF) for the drug to be registered (duly notarized).

1.4 GMP by National Regulatory Authority of the country of origin (duly notarised). 1.5 List of countries where marketing authorization or import permission for the said drug is granted with date

1.6 List of countries where marketing authorization or import permission for the said drug is cancelled/withdrawn withdate.

1.7 List of countries where marketing authorization or import permission for the said drug is pending since (date).

1.8 Domestic price of the drug in the currency following in the country of origin.

1.9 List of countries where the said drug is patented.

Requirements of Schedule D II

Chemical & Pharmaceutical Information of the drugs-

chemical name, generic name ii) dosage form, composition, source, specifications & tests for identification iii) documentation on pack size, storage condition, safety documents on containers & closures, iv) manner of labeling & package v)three samples of drug/product & outer packing with batch certificate to be submitted, vi) batch test reports of five consecutive production batches to submitted for every site of manufacturing.

Biological & Biopharmaceutical information of drugs-

biological control tests applied on starting material/intermediate products/finished products, ii) stability of finished product, iii) sterility & pyrogen test specification & protocol designs, iv) acute & sub acute toxicity test & specification & protocol, v) date relating to bioavailability studies & bio equivalence, vi) any other relevant information

Labeling & packaging information of drugs-

- Labels should as per specification under the acts & rules, ii) package inserts 'd be in English & include following therapeutic indications: posology & method of administration, contraindications, special warnings & special precautions, interactions, whether pregnancy & lactation contraindicated, undesirable effects, antidote for over poisoning, effects on ability to drive & use machines, iii) package insert 'd include information on list of exepients, incompatibilities, shelf life, special precautions for storage, name & specification of the container & instruction for use/handling. Specific information for special products- to be supplied separately in annexures A,B & C.

MANUFACTURE OF DRUGS

Manufacture in relation to any drug or cosmetic, includes any process or part of process for making, altering, ornamenting, finishing, packing, labeling, braking up or otherwise treating any drug or cosmetic with a view to its sale & distribution but does not include the compounding or dispensing of any drug or packing of any drug in ordinary course of retail business

Following licenses are provided for manufacture of drugs under D&C Act

1. Drugs other than those specified in Schedule C, C_1 & X
2. Drugs specified in Schedule C, C_1 but not specified in Schedule X
3. Drugs specified in Schedule C, & C_1
4. Drugs specific in Schedule X but not in Schedule C & C_1
5. Drugs specified in Schedule C, C_1 and X

6. Drugs for the purpose of examination, test or analysis
7. Loan Licenses
8. Repacking Licenses
9. Blood products

Repacking is also a manufacturing for the purpose of the act.

If drugs are manufactured in more than one set of premises, a separate application is to be made & separate licenseshall be issued in respect of each such premises.

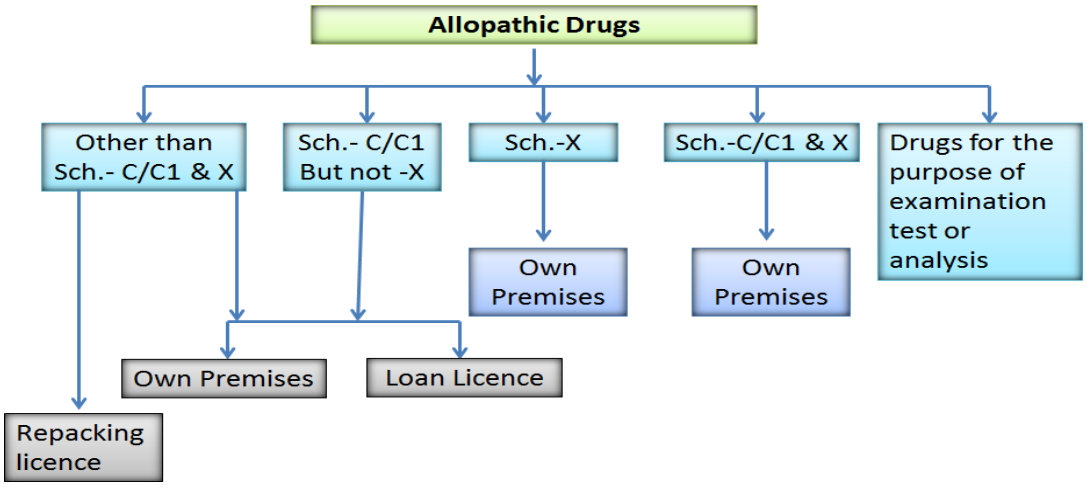
Licenses for manufacture or sale or distribution of drugs are granted or renewed by Central License Approving Authority(CLAA) appointed by the central government.

CLAA can delegate his power of signing licenses to any other person under his control with approval of the CentralGovernment.

Manufacture

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

Types of manufacturing licenses



Prohibition of manufacture

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

Prohibition for the manufacture & sale of Certain Drugs

- From the date notified by the State Government, no person shall himself manufacture for sale or distribution orsell or distribute-
  - ✓ Any **drug** which is not of standard quality or is misbranded, adulterated or spurious;
  - ✓ Any cosmetic which not of standard quality or is misbranded, adulterated or spurious;
  - ✓ Any **patent** or proprietary medicine whose formulae is not disclosed on ***label*** or the container;
  - ✓ Any drug which purports to cure, mitigate or prevent 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 thereunder;
  - ✓ Any drug or cosmetic which has been imported or manufactured in contravention of the provisions ofthis Act or Rules thereunder or in contravention of the conditions of a license.
- Every person not being manufacturer of a drug or cosmetic or his agent for the distribution shall if so required disclose to the inspector the name address and other particulars of the person from whom he procured the drugor cosmetic.
- A drug or cosmetic shall not be rendered to be misbranded, adulterated or spurious or below standardquality, if-

-There has been added thereto some innocuous substance or ingredient required for its manufacture or preparation asan article of commerce in state fit for carriage or **consumption**, & not to increase the bulk, or weight or measure of thedrug or *cosmetic or to conceal its inferior quality or other defect.*

-In process of manufacture, preparation or conveyance some **extraneous substance has been unavoidably become inter-mixed with it,** however this does not apply in relation to any sale or distribution of the drug or cosmetic occurringafter the vendor or distributor becomes aware of such inter-mixture.

- There are two types of conditions for all manufacturing licenses

-Conditions which are to be satisfied ***before*** a license is granted

-Conditions which are to be satisfied ***after*** the license is granted.

Manufacture of Drugs other than those specified in Schedule C & C1

- Application for the grand or renewal of license for the manufacture of drugs other than those specified in schedule C, c1 & X 'd be made to LA in Form 24 & for manufacture of Schedule X drugs in Form 24F. Respectivelicenses are issued in form 25 & 25F
- Application for grand/renewal of such license shall be made for up to 10 items in each category in Form 24-Aaccompanied by fee of 6000 & an inspection fee of Rs. 1500 to LA & license shall be issued in Form 25A.
- Additional fee of Rs 300 per item is payable for each additional item
- License in form 25 or 25F remains valid for a period of 5 **years** on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made within 6 months of expiry, afterpayment of additional fee, the license shall continue to be valid
- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

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 **Manufacture 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 **Schedule-F**
- Some classes should be tested for **aerobic & anaerobic micro-organism**.eg. Sera, Insulin, Pituitary hormones.
- Serum should be 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 drugs specified in Schedule C, C1 & X

- Application for the license of manufacturing drugs specified in Schedule C, C1 excluding those specified in Schedule X should be made to the LA in Form 27 & for manufacture of drugs specified in Schedule C, C1 & X infor 27B. Respective licenses are issued in Form 28 & 28B.
- Application for including any additional drug in the license should be accompanied by a fee of **Rs.50 for eachdrug subject to a maximum of Rs.500**
- Conditions for the grant of license: Before the grand of license, the following conditions must be complied bythe applicant

1. The manufacture will be conducted under the active direction of a competent technical staff consisting at least oneperson who is a full time employee & who is

-A graduate in pharmacy/pharmaceutical chemistry of a recognized University with at least ***18*** **months** practical experience after graduation in manufacture of drugs to which this license applies.

-A graduate in science of a recognized University who passed in degree with **chemistry** or **microbiology** as principal subject & had al least *3 years experience* in the manufacture of drugs to which the license applies.

C,C1 …27 C,C1,X.....27B

-A graduate in **medicine** of a recognized University with at least 3 years' experience in manufacture of relevant drugs; or

-A graduate in chemical engineering of a recognized University with at least 3 years' experience in manufacture ofrelevant drugs; or

-Holding any foreign qualification comparable in quality, content and training with above qualifications & is permitted towork as competent staff by Central Government

1. The factory conditions must comply with the conditions prescribed in Schedule M and M3
2. Applicant should provide adequate space, plant & equipment for any or all manufacturing operations as prescribed inSchedule M & M3
3. Applicant should provide adequate **staff, premises and laboratory equipment** for carrying out such tests for strength,quality & purity of substances as required under the rules.

4. Adequate facilities for the **storage** of manufactured drugs should be provided.
5. *Data on stability of drugs that may deteriorate, for fixing the date of expiry shall be furnished to LA.*
6. Licensee shall comply with requirements of **GMP**.
7. For manufacture of patent or proprietary medicines, data should be provided to LA that justifies that the medicines are: stable under conditions of recommended storage. contains such ingredients & in such quantities for which there is therapeutic justification

- License in form 28 & 28B remains valid for a period of 5 years on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made within 6 months of expiry, afterpayment of additional fee, the license shall continue to be valid
- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.
- ***Large Volume Parenteral*** means the sterile solutions indented for parenteral administration with a volume of100 ml or more in one container of the finished dosage form indented for single usage.

Conditions of the License

1. Licensee should provide & maintain, adequate staff & adequate premises and plant for the proper manufacture& storage of substances
2. Licensee should maintain records of the manufacture as per particulars given in schedule U.
3. Licensee should allow Inspectors to enter any premises where manufacture is carried on & to inspect the processof the manufacture.
4. Licensee should allow inspectors to inspect all registers and records maintained under these rules & to takesamples of manufactured product
5. should allow the LA to inspect if any changes in expert staff & any material changes in premises or plant sincedate of last inspection.
6. On request by LA licensee should furnish form every batch, a sample of adequate quantity for any examination
7. If any batch has been found out by LA not to confirm with the standards, licensee should withdraw the remainderof batch from sale.
8. should maintain a Inspection book to enable inspector to record his impression.
9. should maintain reference samples of each batch of drugs manufactured by him, in a quantity twice

than thatsufficient for conducting all tests.

10. should forward to LA of state a statement of sales effected to manufacturers, wholesalers, retailers, hospitals,nursing homes, dispensaries every three months.

Manufacture of Schedule-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 XRx
- Marketed in packings **not exceeding**
- 100 unit dose –Tablets/Capsules
- 300 ml- Oral liquid
- 5 ml - Injection

Manufacture of Drugs for Examination, Tests or Analysis

- License is necessary for the manufacture of any drug in small quantity for the purpose of examination, test oranalysis.
- If a person proposing to manufacture does not hold license i) to manufacture drugs other than those specified inSchedule C, C1 & X, or ii) to manufacture drugs specified in Schedule C, C1 in respect to such drugs; he should obtain license in Form 29.
- If drug is not recognized as safe for use, license in Form 29 is only granted after producing no objectioncertificate from LA appointed by Central Government.
- License remains valid for a period of one year time
- Drugs should be kept in containers bearing labels indicating the purpose for which it has been manufactured.
- If the drugs are to be supplied, it should bear label stating name & address of manufacturer, scientific name ofsubstance & purpose for which it has been manufactured.

Conditions for License

1. Drugs should be used exclusively for the purpose for which they are manufactured
2. Licensee should allow inspector to inspect the premises & satisfy himself that only examination, test oranalysis is being conducted.

3. Licensee should keep **record** of quantity of drugs manufactured and supplied to any person.
4. Licensee should maintain inspection book to enable inspector to record his impression and defectsnoticed.
5. Licensee must comply with any rules made subsequently and of which the LA has given him NLT **onemonths**' notice.

Manufacture of New Drugs

- Defined as a drug the composition of which is such that it is **not generally recognized among experts as safe foruse under conditions recommended; or**
- Suggested on the label & includes any drug the composition of which is such that the drug as a result of investigations for determining its safety for use under such conditions, is so recognized but which has not otherwise than during course of such investigations, been used to any large extend for any appreciable lengthof time under the said conditions
- Provisions applicable for the manufacture of new drugs whether classifiable under schedule C & C1 or otherwise:

-No new drug can be manufactured unless prior approval of the LA has been taken.

-Applicant should produce all documentary & other evidence relating to the standards of quality, purity, strength & such other information as may be required including the results of therapeutic trials carried out on the new drug.

-While applying for a license to manufacture a new drug, or its preparations an applicant should produce along with hisapplication evidence that the drug has already been approved.

Loan License

Definition:

A person (applicant) who does not have his own arrangements (factory) for manufacture but who wish to manufacturingfacilities **owned by another licensee**. Such licenses are called Loan licenses.

Licence is obtained from licensing authority (FDA) on application in prescribed **forms (24-A, 27-A)** with prescribed fees.Loan licenses are issued for:

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

2) Drugs specified in Schedule-C/C1

- A loan license means a license which a LA may issue to a applicant who does not have his own arrangements formanufacture but who intends to avail himself of the manufacturing facilities owned by another licensee.

- Issued for the manufacture for sale or distribution of drugs other than those specified in Schedule C, C1 & X.
- Application for license is made in Form **24-A & the license is issued in Form 25-A**.
- Before grant of license, the LA shall get the premises inspected by one or more inspectors.
- Inspector shall check into all the portions of the plant & shall also inquire in professional qualification for thetechnical staff employed.
- **For the manufacturing of additional items, an application must be made to LA.**
- Licensee is required to test each batch of raw materials & finished products & the records must be maintained for a period of **5 yrs from the date of manufacture. (2yrs in case of drugs having expiry date, from the date ofexpiry**)
- Loan license is **deemed to be cancelled or suspended if license owned by loan licensee, whose manufacturingfacilities is been availed by licensee is cancelled or suspended**.

Repacking Licenses

Repacking license are granted for breaking up of any drug other than those specified in Schedule C, & C1, on applicationto LA in Form **24B** & license is issued in Form **25B** subject to satisfying the following conditions:

1. The repacking operation must be carried out under hygienic conditions & under supervision of competent staffnamely,
   a) A person who holds an approved **Diploma in Pharmacy or is an Registered Pharmacist.**
   b) A person who has passed intermediate examination with **Chemistry as principal subject.**
   c) A person who has **passed matriculation & has at least 4 yrs**. practical experience in manufacturing,dispensing or repacking of drugs.
2. Factory conditions must specify conditions prescribed in Schedule M.
3. Applicant must have in his premises adequate facilities for the testing of drugs. Which is separate from therepacking unit.
4. License must be kept at licensed premises & produced on request of DI
5. 5. Any change in competent staff must be reported to LA
6. 6. For repacking of any additional items, application must be made to LA.
7. 7. The label on repacked drugs should mention the name & address of the licensee & his license numberpreceded by the word '**Rpg. Lic. No."**
8. 8. The license remains valid up to **31st December** of the year following the year in which it is grated.

Definition:

Process of **breaking up** any drug from a bulk container into small packages and labeling with a view to their sale anddistribution.

Repackaging of drugs is granted of drugs other than Schedule-C/C1 and X.

Penalties Related to Manufacture

OFFENCES	PENALTIES
Manufacture of any **spurious** drugs	a) 1-3 years imprisonment and Rs.5000 fine b) 2-6 years imprisonment & Rs.10000 fine on subsequentconviction
Manufacture of **adulterated drugs**	a) 1 year imprisonment & Rs.2000 fine b) 2 years imprisonment & Rs.2000 fine for subsequentconviction
Manuf. of drugs in **contravention** of theprovisions	a) Imprisonment up to **3 months & Rs.500** fine b) Imprisonment up to **6 months & Rs.1000** fine onsubsequent conviction

Manufacture of cosmetics

Prohibited for the following classes :

- **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**

Drugs Inspector

Qualification

1 Persons having qualification for appointment as government, as Governmental Analysis for allopathic drugs; or

2 having a degree in ayurveda, siddha or unani system and not less than three years of post-graduate experience inthe analysis of drugs in a laboratory under control of (a) a government analyst, or (b) a chemical examiner, or (c) head of an institution specially approved for this purpose.

Power:

a) **Inspect, --**

(i) Any premises where in any drug or cosmetic is being manufactured.

(ii) Any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

Take samples of any drug or cosmetic,--

(i) Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

(ii) From any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to apurchaser or a consignee.

Appointed by Central and State Governments.

He should be a person with out any financial interest in the import, manufacture or sale of drugs or cosmetics.They are deemed as public servants and are officially subordinate to the Controlling Authority.

Qualifications

For appointment as DI, person must have a degree in Pharmacy/Pharmaceutical Chemistry/Medicine with specializationin Clinical Pharmacology/Microbiology from a recognized University;

For inspection of manufactured substances in Schedule C, the DI must have 1) at least 18 months experience in manufacture of at least one of the substance specified in schedule C 2) at least 18 month experience in testing one ofthe item in schedule C 3) gained experience of NLT 3 yrs in inspection of firms manufacturing any of the substances ofSchedule C during their tenure as services as DI

Powers of DI He can Inspect

- any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizingand testing the drug or cosmetic;
- any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, ordistributed ; Take samples of any drug or cosmetic
- which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;
- from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to apurchaser or a consignee;

At all reasonable times with necessary assistance

search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect ofwhich an offence relating to manufacture sale or distribution has been, or is being, committed;

or

- Enter and search any place in which he has reason to believe an offence relating to manufacture, sale ordistribution of drugs or cosmetics has been, or is being committed; or
- stop and search any vehicle, vessel, or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence has been, or is being, committed, and order in writing the person in possession of the drug or cosmetic not to dispose of any stock that of for a specified period not exceeding 20 days or, unless the alleged offence is such that the defect may be removed by the possessor ofthe drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been ,or is being, committed
- Examine any record, register, document or any other material object with any person or in any place mentionedabove and seize the same if it is likely to furnish the evidence as an offence
- Require any person to produce any record, register, or other document relating to the manufacture for sale orfor distribution of any drug or cosmetic with respect to which an offence has been committed
- Exercise such other powers as may be necessary for carrying out the purposes of the Acts or Rules.

Duties of Inspectors

A) Inspection of premises licensed for sale:

- Inspect NLT twice an year all establishments licensed for sale of drugs within the area assigned to him and tosatisfy himself that the conditions of license are being observed.
- Procure and send for tests or analysis, if he has reason to think that the drugs are sold in contravention ofprovisions of Acts or Rules.
- To investigate any complaints made to him in writing & to institute prosecutions in respect to the breaches ofthe act.
- To maintain all records of inspections made & actions taken by him including taking of samples and seizure ofstocks & to submit copies of such records to the Controlling Authority
- To make enquiries and inspections as may be necessary to detect sale of drugs in contravention to the Act.

- When so authorized by State Governments to obtain imported packages which he has reason to suspect tocontain drugs whose import is prohibited.

B) Inspection of Manufacture of Drugs

- Inspect NLT twice a year all premises licensed for the manufacture of drugs within the area allotted to him and satisfy himself that the condition of license and provisions of Acts and Rules are observed.
- In establishments licensed to manufacture products specified in Schedule C and C1 inspect the process of manufacture, means employed for standardizing and testing of drugs, methods & place of storage, technical qualifications of staff employed & all details of location, construction & administration of establishment likely toaffect the potency or purity of drug.
- To send controlling authority after each inspection a detailed report indicating conditions of license & provisionsof Acts & Rules which are being observed & which are being not observed.
- To take samples of drugs manufactured on premises & send them for test or analysis.
- To institute prosecutions in respect of breaches of Act and Rules.

Procedure for Drug Inspectors

- An Inspector taking any samples must pay its fair price & may require written acknowledgement for the same. Ifprice tendered is refused or when Inspector seizes any stock of any drug or cosmetic, he should issue the receiptfor the same in prescribed form. (Form 16)
- He should inform the concerned person, the purpose of taking the sample in form 17 & divide the sample to four parts In his presence. Each portion is then sealed & suitably marked. The person from whom the sample is taken must also be allowed to add his mark of seal on the packet. If sample taken from a manufacturing premises, it should be divided to three portions only.
- The sample if made into small volume is likely to deteriorate, Inspector can take three or more containers whennecessary after suitably marking it.
- One portion of sample is to be restored to the person, second part send to Government analyst and third one ispreserved for production before the court, if required & fourth is sent to warrantor if any.
- Inspector should sent sample to Government Analyst by registered post or by hand in sealed packet enclosed together with memorandum in Form 18 in an outer cover addressed to Government analyst.
- If the confiscated drug is not of standard quality, it should be reported to court accordingly & court may orderdestruction of drug under the supervision of Inspector in presence of such authority that the court may prescribe.

- If confiscated drug is of standard quality, Inspector may report court accordingly and court may order sale ofdrugs by public auction to any party holding a requisite license.
- Any record, register or any other document sized by the Inspector should be returned to the persons fromwhom they where seized or who produce the same within a period of 20 days of such seizure or produce.
- When an Inspector seizes any record, register or document, or any other material object, he should as soon asinform the same to the judicial magistrate & take his orders to the custody thereof.
- Every person for time being in charge of any premises where any drug or cosmetic is manufactured or is kept forsale or distribution, on being required by the Inspector is legally bound to disclose to the inspector the place where drug or cosmetic is being manufactured or kept.
- Willfully obstructing the Inspector or refusing to provide any record or register is punishable with imprisonmentup to three years, or with fine or both.

Schedules to the rules

TYPE	CONTENT
"A"	Performa for **forms**(Application, issue, renewal, etc.) manufacture for sale/distribution of Allopathic drugs, Loan Licence, re-packing for sale, operate a Blood Bank , manufacture for sale orfor distribution of LVPs etc
"B"	**Rates of fee** for test or analysis by CDL or Govt. analysts
"C"	List of **Biological and special products (Injectables)** applicable to special provisions. Sera. Solution of serum proteins intended for injection, Vaccines for parenteral injections. Toxins,Antigen. Antitoxins
"C1"	List of Biological and special products **(non-parenteral)** applicable to special provisions. Ergotpreparations, Adrenaline, Fish liver oil, Vaccines etc
"D"	List of drugs that are **exempted** from provisions of **import**

"E1"	List of poisonous substances under the **Ayurvedic , Siddha and Unani systems**
"F"	Provisions applicable to **blood bank**
"F1"	Special provision applicable to biological and special products, eg. Bacterial and viral vaccines,sera from living animals, bacterial origin diagnostic agents
"F2"	Standards for surgical dressings, Gauze or other dressings used to cleanse a wound, Skin sealantsor barriers, Solutions used to moisten gauze
"F3"	Standards for sterilized umbilical tapes
"FF"	Standards for ophthalmic preparations
"G"	List of substances required to be used under medical supervision and labelled accordingly
"H"	List of substances (prescription) that should be sold by retail only on prescriptions of R.M.P.
"J"	List of diseases and ailments that drug should not claim to cure. AIDS, Angina Pectoris, Appendicitis, Arteriosclerosis, Blindness, Blood poisoning, Bronchial asthma, Cancer and benign tumour, Cataract, Spondylitis, Stammering, Stones in gall-bladder, kidney, bladder, Vericose vein
"K"	List of drugs that are exempted from certain provisions regarding manufacture. Analgesic Balms, Antacid preparations, Gripe Water for use of infants, Inhalers, containing drugs for treatment of cold and nasal congestion, Syrups, lozenges, pills and tablets for cough, Liniments for external use, Skin ointments and ointments for burns, Absorbent cotton wool, bandages absorbent guazeand adhesive plaster.
"M"	Requirements of manufacturing premises, GMP requirements of factory premises, plants andequipments
"M1"	Requirements of factory premises for manufacture of Homeopathic medicines
"M2"	Requirements of factory premises for manufacture of cosmetics

"M3"	Requirements of factory premises for manufacture of medical devices
"N"	List of equipment to run a Pharmacy
"O"	Standards for disinfectant fluids
"P"	Life period(expiry) of drugs
"Q"	Coal tar colors permitted to be used in cosmetics. Guinea GreenB, Tartrazine, Sunset yello FCF,Amaranth, Erythrosine etc
"R"	Standards for mechanical contraceptives
"R1"	Standards for medical devices
"S"	Standards for cosmetics
"T"	Requirements (GMP) of factory premises for Ayurvedic, Siddha, Unani drugs
"U"	Manufacturing and analytical records of drugs
"U1"	Manufacturing and analytical records of cosmetics
"V"	Standards for patent or proprietary medicines
"W"	List of drugs marketed under generic names- Omitted
"X"	List of narcotic drugs and psychotropic substances
"Y"	Requirement and guidelines on clinical trials for import and manufacture of new drugs

Summary

- Location of factory & its surroundings should ensure freedom from contamination due to sewage drain, etc &obnoxious odors or fumes, or large quantity of soot, dust or smoke.

- Factory building should be constructed to ensure production of drugs under hygienic conditions
- Should be designed to allow the production preferably in uni-flow & with logical sequence of operations.
- The equipment's and materials must be placed orderly & the movement of personnel must be restricted toavoid cross contamination
- All manufacturing operations must be carried out under the supervision of competent technical staff. Critical steps in the process related to selection, weighing & measuring of raw materials must be done under the directsupervision of competent technical staff
- Printed labels & packaging materials including leaflets'd be handles & accounted to ensure that they do not become intermixed. Prior to issue, they should be examined & released as satisfactory for use by quality controlpersonnel.
- Records for the distribution of each batch of drug should be maintained in order to facilitate prompt &complete recall of the batch if necessary.
- Design and construct the facilities and equipments properly
- Follow written procedures and Instructions
- Document and validate work
- Monitor facilities and equipment
- Write step by step operating procedures and work on instructions
- Design, develop and demonstrate job competence
- Protect against contamination
- Control components and product related processes
- Conduct planned and periodic audits
- Classes of drugs prohibited to be sold includes wholesale of biological (C/C1)
- Wholesale of other than those specified in C/C1 and X
- Restricted license is granted to those dealers who do not engage the services of a qualified person and only dealwith such classes of drugs whose sales can be effected without qualified person and vendors who do not have fixed premises
- Adequate premises, with greater than 10 M^2 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
- DTAB advises the Central Government and the State Governments on technical matters.
- To carry out the other functions assigned to it by this Act
- CDL Established in **Calcutta**, under the control of a director appointed by the Central Government
- DCC is an **advisory body** constituted by central government
- Govt. Analysts are officers appointed by the central or state government and perform the duties
- Licensing Authority inspect all establishments licensed for the sale of drugs within the area
- 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
- License is necessary for the manufacture of any drug in small quantity for the purpose of examination, test oranalysis.
- If a person proposing to manufacture does not hold license i) to manufacture drugs other than those specifiedin Schedule C, C1 & X, or ii) to manufacture drugs specified in Schedule C, C1 in respect to such drugs; he shouldobtain license in Form 29.
- A person(applicant) who does not have his own arrangements(factory) for manufacture but who wish tomanufacturing facilities owned by another licensee. Such licenses are called Loan licenses.
- Repacking license are granted for breaking up of any drug other than those specified in Schedule C, & C1, onapplication to LA in Form 24B & license is issued in Form25B
- Persons having qualification for appointment as government as Governmental Analysis for allopathic drugs ; or having a degree in ayurveda, siddha or unani system and not less than three year post graduate experience in the analysis of drugs in a laboratory under control of (a) a government analyst, or (b) a chemical examiner, or (c)head of an institution specially approved for this purpose
- They can Inspect, any premises where in any drug or cosmetic is being manufactured
- Any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, ordistributed

  Import of drug under license

  1)Specified in Schedule-C/C12)Specified in Schedule-X

  3)Imported for Test/Analysis 4)Imported for personal use5)Any new drugs
- Schedules A, B C, C1, D, E, F, F1, F2, FF, G, H, K, M, M1, M2, N, O, P, Q, R, S, T, U, V, Y

Advisory :

1)Drugs Technical Advisory Board-DTAB

2)Drugs Consultative Committee-D.C.C.

B) Analytical :

1) Central Drugs Laboratory - CDL

2)Drug Control

2) Laboratory in states

3)Government Analysts

C) Executives :

1. Licensing authorities
2. Controlling authorities
3. Drug Inspectors

Includes

a) all medicines used for the internal or external use of human beings or animals and all substances indented to be used for or in diagnosis, treatment , mitigation or prevention of any disease or disorder in human beings or animals including preparation applied for repelling mosquitoes

b) substances indented to affect the structure or any function of human body or indented to be used for thedestruction of vermin or insects that cause disease in human beings or animals

c) all substances indented for use as components of drug including empty gelatin capsules

d) devices indented for internal or external use in the diagnosis, treatment, mitigation or prevention of diseaseor disorder in human beings or animals.

- Definitions of cosmetics, spurious, adulterated drugs and cosmeticsIf drugs are manufactured in more than one set of premises, a separate application is to be made & separate license shall be issued in respect of each such premises
- Licenses for manufacture or sale or distribution of drugs are granted or renewed by Central License ApprovingAuthority (CLAA) appointed by the central government
- From the date notified by the State Government, no person shall himself manufacture for sale or distribution or sell or distribute- Any drug which is not of standard quality or is misbranded,

adulterated or spurious

- Any cosmetic which not of standard quality or is misbranded, adulterated or spurious
- Any patent or proprietary medicine whose formulae is not disclosed on label or the container
- Any drug which purports to cure, mitigate or prevent any disease specified in Schedule J

Short answers (2 marks):

1. Write any two offences and penalties for sale of drugs.
2. Enumerate two functions of PCI Inspector.
3. Give the labelling requirements and write specimen label for schedule G.
4. What is Drug Consultative Committee (DCC)?
5. Write a note on repacking license.
6. Enumerate schedule B.
7. Write the types of retail sale of drugs. Give two examples of schedule J.
8. Write a short note on Drug Control Laboratory.
9. What is schedule G & N.?
10. Write the labelling requirements for ophthalmic preparation.

Short essays (5 marks):

1. Write a note on retail sale.
2. Write a note on schedule M.
3. Write a note on Central Drug Laboratory (CDL).
4. Define and write the qualifications and duties of government analyst.
5. Write a note on general labelling requirements and give the specimen labels for schedule X drugs.
6. Describe about restricted license.
7. What are qualifications and duties of Drug Inspector?
8. Describe the general requirements of labelling under Drugs and Cosmetics Act 1940.
9. Describe schedule P, U & V under Drugs and Cosmetics Act 1940.
10. Explain in brief about wholesale and retail sale under D&C Act
11. Give the specimen label for schedule H with suitable example.
12. Explain in brief about controlling authority as per D&C Act.
13. Write a short note on schedule F.
14. Write the labelling requirements of medicines for internal use with a model labelling.

Long essays (10 marks):

1. Explain briefly about schedule Y.
2. Explain in detail about schedule M.
3. Discuss briefly about clinical trials as per schedule Y.

4. Write the constitution and functions of Drug Technical Advisory Board (DTAB).