Program Name	**:**	**B. Pharm**
Course Name	**:**	**Pharmaceutical Jurisprudence**
Course Code	**:**	**BP505T**
Semester	**:**	**Vth**
Session	**:**	**2020-2021**
Unit	**:**	**1 (Part II)**
Topic	**:**	**Manufacture, Sale and Distribution of drugs and cosmetics Provisions relating to Manufacturing of drugs**
Sub-topic	**:**	Prohibition of manufacture and sale of certain drugs Conditions for grant of license and conditions of license for manufacture of drugs Manufacture of drugs for test, examination and analysis, manufacture of new drug, Loan license and repacking license.

Manufacture, Sale and Distribution of drugs and cosmetics

Provisions relating to Manufacturing of drugs

Following categories of licences are granted for the manufacture of drugs-

1. Licence for the manufacturing of Schedule C and C(i) drugs

2. Licence for the manufacturing of drugs other than Schedule C and C(i) and X drugs.

3. Licence for the manufacturing of Schedule X drugs.

4. Licence for the manufacturing of Schedule C, C(i) and X drugs

5. Loan licence for the manufacturing of above categories.

6. Repacking licence.

Conditions for the manufacture of drugs specified in Schedule C and C(i) drugs

A licence is required for the manufacture of drugs specified in Schedule C and C(i) drugs. For the manufacture of Schedule C and C(i), an applicant has to make application to the licensing authority in Form 27 and licence is granted in Form 28. Before granting such licence, licensing authority shall satisfy the following conditions-

1. The premises meant for the manufacture of drugs specified in Schedule C, C(i) shall be an adequate and equipped with the proper storage accommodations under the direction and supervision of competent and technical staff along with separate analytical laboratory and separate technical staff.

2. There shall be separate arrangements for the manufactured drugs.

3. For fixing expiry, there shall be a separate stability data.

4. A licence shall be granted for patent and proprietary medicine if data is justifying that it is safe, effective and stable.

Licensee shall satisfy the following special conditions

1. Licensee shall provide adequate technical staff for the manufacture and testing of Schedule C and C(i) drugs.

2. Any licensee who is handling culture, pathogenic spore bearing organism shall provide separate laboratory, utensil and apparatus.

3. Licensee shall maintain records and registers of the analytical test and manufacturing as per Schedule U for five years from the date of manufacturing.

4. Licensee shall allow an inspector to enter and inspect any manufacturing premises, process of manufacturing and means employed for testing and standardizing drugs.

5. Licensee shall maintain the inspection book in Form 35.

6. Licensee shall inform the licensing authority any change in the constitution of firm or staff.

7. Licensee shall maintain reference sample from each batch of drug manufactured by him.

8. Licensee shall provide proper storage accommodations for preserving the properties of drugs.

9. Licensee shall manufacture only standard quality drugs as per Schedule Second.

Conditions for the manufacture of drugs other than those specified in Schedule C, C and X drugs

A licence is required for the manufacture of drugs other than those specified in Schedule C, C(i) and X drugs. For the manufacture of such drugs, an applicant has to make application to the licensing authority in Form 24 and licence is granted in Form 25. Before granting such licence, the licensing authority shall satisfy the following conditions-

1. The manufacture shall be conducted under the direction and supervision of competent and technical staff consisting of at least one person who is whole time employee and shall be -

a. Graduate in pharmacy or pharmaceutical chemistry of a recognized university with not less than 18 months experience in manufacture of drugs after graduation; or

b. Graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university with not less than 3 years' experience in manufacture of drugs; or

c. Holds any other prescribed qualifications which is equivalent to (a) and (b) granted by an authority outside India.

2. The factory premises shall be as per the guidelines of GMP and shall satisfy the conditions specified in Schedule M.

3. Manufacturer shall provide adequate space, plant, equipment's, etc for the manufacture of variety of drugs as per the Schedule M.

4. Manufacturer shall provide a separate analytical laboratory along with staff and equipment's for testing the strength, quality and purity of raw materials and finished products.

Conditions to be satisfied by licensee for the manufacture of drugs other than those specified in Schedule C, C(i) and X drugs

1. The licensee shall maintain records and registers of the analytical test and manufacturing as per Schedule U for five years from the date of manufacturing.

2. The licensee shall allow an inspector –

a. to enter the manufacturing premises.

b. to inspect the premises licensed for the manufacture and test of drugs.

c. to check all the registers and records used for the manufacture of drugs.

d. to take the samples of drugs, if necessary.

3. Licensee shall inform the licensing authority any change in the constitution of firm or staff.

4. Licensee shall manufacture only such drugs that are directed by licensing authority.

5. Licensee shall maintain the inspection book in Form 35 and shall also reference sample from each batch.

Conditions for the manufacture of drugs specified in Schedule X (Form 25 or 25F)

A separate licence is required for the manufacture of drugs specified in Schedule X. For the manufacture of such drugs an applicant has to make application to the licensing authority in Form 24-F accompanied with the prescribed fees and licence is granted in Form 25-F. Applicant has to satisfy the following conditions -

1. The licensee shall forward to the licensing authority a statement of supply of drugs, sales of drug to the manufacturer, wholesaler, retailer, hospital, dispensaries, nursing homes and Registered Medical Practitioners every three months.

2. The licensee shall store drug in custody under direct supervision of responsible person.

3. The licensee shall maintain the accounts of all transactions for five years.

4. The licensee shall provide and maintain staff, premise and the equipment as specified.

5. The licensee shall comply with the provisions of the Act and of these rules.

6. The licensee shall either in his own laboratory or in any other laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his products and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of 5 years from the date of manufacture.

7. The licensee shall allow an inspector to enter, any premises and to inspect the plant and the process of manufacture and the means employed for standardizing and testing the drugs.

8. The licensee shall allow an inspector to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs.

9. The licensee shall, from time to time, report to the licensing authority any changes in the expert staff responsible for manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose.

10.The licensee shall, on request, furnish to the licensing authority or the controlling authority direct, from every batch or batches of drugs, a sample of such quantity as may be considered adequate by such authority for any examination and if so required, also furnish full protocols of tests which have been applied.

11. The licensee shall on being informed by the licensing authority that any part of any batch of the drug has been found by the licensing authority not to confirm with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale.

12.The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

13.The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency and where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.

14.The licensee, who has been granted a license in Form 25-F, shall-

(i) forward to the licensing authority of the concerned States of manufacture and supply of the drug a statement of the sales effected to the manufacturers, wholesalers, retailers, hospitals, dispensaries and nursing homes and Registered Medical Practitioners every three months;

(ii) maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered and such records shall be retained for a period of five years or one year after the expiry of potency, whichever is later: -

A. Accounts of the drugs specified in Schedule X used for the manufacture: -

1. Date of issue.
2. Opening balance of stock on the production day.
3. Quantity received, if any, and source from where received.
4. Quantity used in manufacture.
5. Balance quantity on hand at the end of the production day.
6. Signature of the person in charge.

B. Accounts of production: -

1. Date of manufacture.
2. Name of the drug.
3. Batch Number.
4. Quantity of raw material used in manufacture.
5. Anticipated yield.
6. Actual yield.
7. Wastage.
8. Quantity of the manufactured goods transferred.

C. Accounts of the manufactured drugs:

1. Date of manufacture.

2. Name of the drug.

3. Batch Number.

4. Opening Balance.

5. Quantity manufactured.

6. Quantity sold.

7. Name of the purchaser and his address.

8. Balance quantity at the end of the day.

9. Signature of the person in charge.

15. The licensee shall store drugs specified in Schedule X in bulk form and when any of such drug is required for manufacture in a place other than its place of storage it shall be kept in a separate place under the direct custody of a responsible person.

16. The licensee shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M

Conditions of licence for the manufacture of drugs specified in Schedule C, C(i) (excluding Schedule X and part XB) and those specified in Schedule X

A licence to manufacture for sale or for distribution of drugs specified in Schedule C, C(i) other than large volume parenteral, sera and vaccines, drugs specified in part XB and drugs those specified in Schedule X shall be issued in Form 28 and a licence to manufacture for sale or for distribution of drugs specified in Schedule C, C(i) and X (other than large volume parenteral, sera and vaccines, drugs specified in part XB and drugs) shall issue in Form 28B. A licence to manufacture for sale or for distribution of large volume parenteral, sera and vaccines shall be issued in Form 28D.

Before the grant of such licence, licensee shall comply with the general conditions specified for grant of licence in Form 25 or 25F. Applicant shall provide information to

the licensing authority about data on stability of drugs which are likely to deteriorate for fixing the data of expiry which shall be printed on the labels.

Conditions of Licence for Allopathic Loan Licence Manufacturing (Rule 74B)

A loan licensee, who avails the manufacturing facilities to a person for the manufacture of drugs other than those specified in Schedule C, C(i) and X and for drugs other than those specified in Schedule X shall be issued in Form 25Aand 28Arespectively.

Conditions of loan licence

1. The licence shall be deemed to be cancelled or suspended, if the license owned by the licensee whose manufacturing facilities have been availed of by the licensee is cancelled or suspended as the case may be, under these rules.

2. The licensee shall comply with the provisions of the Act and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV of the Act. Provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

3. The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U.

4. The records or registers shall be retained for a period of five years from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and rules have been observed.

5. The licensee shall provide and maintain to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out tests of strength, quality and purity of the substances manufactured by him; or

6. The licensee shall make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by the institution.

7. The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.

8. The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

Duration of loan licence

An original loan licence in Form 25-A or a renewed loan licence in Form 26-A unless sooner suspended or cancelled, shall be valid for a period of five years on and from the date on which it is granted or renewed.

Repacking Licence

Repacking licence means the licence which is granted by the authority for the purpose of breaking up of any drug from the bulk container into a small package and labeling of each package with a view to its sale and distribution. Drugs specified in Schedule C and C(i) cannot be repacked. Licence for repacking of drugs against application in Form

24-B (repacking of drugs excluding those specified in Schedule X) shall be granted in Form 25-B.

Conditions to be satisfied by applicant before the grant of repacking licence

1. The repacking operations shall be carried out under hygienic conditions and under supervision of competent person.

2. Factory premises shall comply with the Schedule M requirements.

3. Applicant shall have a separate drug testing unit at his own premises.

However, for test requiring sophisticated instrumentation technique or biological or microbiological methods, licensing authority may permit such tests to be conducted by the institution approved for that purpose by it.

Licensee should satisfy the following conditions:

1. Licensee shall make adequate arrangement for the storage of drugs.

2. Licensee shall allow any inspector to enter and inspect any premises where repacking of drugs is carried out and allow to take samples from such premises.

3. Licensee shall maintain the inspection book in Form 35.

4. Licensee shall allow any inspector to inspect all registers, records and shall supply necessary information whenever required.

5. Licensee shall maintain the reference samples from each batch of drug repacked by him.

6. Licensee shall test each batch or lot of raw materials used by him for repacking.

7. Licensee shall maintain records and registers repacked drugs as per Schedule U for five years from the date of manufacturing.

Classes of prohibited Drugs

The following classes of drugs are prohibited for its manufacture, sale, distribution, etc.

1. Adulterated, spurious, misbranded drug or drug which are not of standard quality.

2. Patent and proprietary medicine of which formula is not disclosed.

3. Drug imported or manufactured in the contravention of the provisions of the Act.

4. Drugs which may claim to cure any of the diseases specified in the Schedule J.

5. Expired drugs.

6. The drugs intended for its consumption by Employees State Insurance Scheme (E.S.I.S) or Government Institutions.

7. Drugs intended for its distribution to the members of the medical profession as free sample and bearing on the container the words **"Physician sample, not to be sold."**

8. Drugs not intended for sale.

Reference:

Yadav, A., Remeth Dias, Vijay Havaldar, and Kailas Mali. *Pharmaceutical Jurisprudence*, 2012.