**TIRUPATI COLLEGE OF POLYTECHNIC AND PHARMACY, RATIA**

**D. PHARMACY SECOND YEAR**

**PHARMACEUTICAL JURISPRUDENCE**

**Section A**

**Question no. 01 (Part-A) Fill in the blanks. Each question carries one mark. 1x10=10**

1) Pharmacy council is reconstituted after every **five** years.

2) A person should have attained the age of **18** years to have his name registered in first register.

3) Schedule H includes **the list of prescription drugs.**

4) Symbol XRX is given for the drugs in **Schedule X.**

5) DTAB stands for **Drug technical advisory board.**

6) The first central council or PCI was constituted in **1949**

7) Drug inspector should inspect a premises licensed for sale of drugs at least **two** times in a year.

8) Production and control of opium is controlled by **Central** government.

9) Pharmacy Council of India has laid down the minimum standard of education required for qualification as a pharmacist, are known as **Education Regulation.**

10) In the state drug laboratory, the analysis is done under the supervision of **Govt. Analyst.**

11) Drug for free distribution to physicians is to be labeled with the words **"Physician sample not to be sold".**

12) List of minimum equipments for efficient running of a pharmacy is laid down in a **schedule N.**

13) Drug and Magic Remedies Act was passed in the year **1955.**

14) Bonded laboratory works under direct control and supervision of **Excise Commmisioner.**

15) The first edition of Indian Pharmacopoeia was published in the year **1955.**

16) Any extract or tincture hemp is called **Medicinal hemp (cannabis).**

17) Central drug laboratory is situated at **Kolkata**.

18) The chairman of DTBA is **Director General of Health Services.**

19) Ganja and Charas are derivatives of ***Cannabis sativa*.**

20) Medicine containing industrial methylated spirit should be labeled '**FOR EXTERNAL USE ONLY'**

21) Examples of two substances notified as poison are **Aconite** and **Arsenic**.

22) Cure for blindness is example of **prohibited** advertisement.

23) RMP stands for **Register Medical Practitioner.**

24) 20 weeks of pregnancy of absorption to be certified by **registered** medical practitioners.

25) DCC stands for **Drug Consultative Committee.**

26) Government opium factories are at **Ghazipur** and **Neemuch.**

27) The elected and nominated members of the council can hold the office for a period of **5 years**

28) Officers of **Central Excise** and **Narcotics** departments are authorized to issue warrants under Narcotic and Psychotropic substances Act.

29) For a non-bonded laboratory the spirit meant for preparation having **Fixed** of excise duty should be stocked separately from spirit meant for preparation with in **bonded lab**.

30) No license is needed for import of drugs other than **those in schedules C, $C_1$ and X**

31) All Schedule C drugs should be tested for **maximum toxicity**

32) Prescriptions containing. **Schedule H and X drugs** should not be dispensed more than once unless prescriber given the direction to do so.

33) The pharmacy council of India shall have a **president** and a **Vice president** elected by the members from amongst themselves.

34) Under Narcotic drugs and Psychotropic substances act, Central Government has to establish **Advisory committee** and also appoint a **Narcotic commissioner.**

35) Ayurvedic preparations containing self generated alcohol in which the alcoholic content does not exceed **2% Proof Spirit** are deemed to be non-alcoholic.

36) Patent medicines cannot be imported unless their **true formula** is given.

37) Repacking of drugs should be carried out under the supervision of **Competent Person.**

38) Drugs containing alcohol should essentially contain the following information on its label **As average % of absolute alcohol by volume.**

39) Psychotropic substances listed in **Schedule III** are exported by declaration in a prescribed format by the Government.

40) Alcoholic preparations can be stored in warehouse for a maximum period of **Three years.**

41) Penalty for use of Govt. analyst report for advertisement is **under drug and cosmetic act 1940.**

42) DTAB consists **of Eight** ex-officio members.

43) A licence is not necessary for manufacture of cosmetics if the employees do not exceed **eight** in number.

44) Pharmacy council of India maintain a register containing names of all persons registered as pharmacists in different states pharmacy council is called as **first register**.

45) Central drug research institute is established at **Lucknow.**

46) The grant of licence for a person who do not have own facility but wishes to avail the facilities existing with another person is called **loan license**.

47) Sample collected by drug inspector will be sent to **Govt. Analyst.**

**48) Morphine** and codeine are opium derivatives.

49) Pharmacy act was introduced in the year **1948.**

50) Schedule M and Y are introduced in **1988**

51) The state pharmacy council has **six** registered pharmacists elected from among themselves.

52) Drug Enquiry committee is also known as **Chopra Committee**.

53) Schedule FF contains **standards for ophthalmic preparations.**

54) Drug bill was introduced in the year **1940**.

55) **Drugs** that are required to be used only under the supervision of a RMP is dealt in Schedule **X**

56) The person incharge of State Drug Laboratory is **Govt. Analyst.**

57) As per **Schedule J** one cannot claim to cure diseases as ailments**.**

58) Drugs which are limitations of substitutes for other drugs are called **spurious drug.**

59) Requirement of factory premises is laid down in schedul**e M.**

60) Education regulations are laid down by **Central Council.**

61) Central registers of pharmacists are maintained by **Registrar of the Central Council.**

62) Drug inspector is appointed under the section of the act **Drug and Cosmetic act, 1940.**

63) Biological and microbiological tests on sera, vaccines and antigens are carried at **Central drug institute, Kausali.**

64) Tests on condoms are carried out at **CDRI, LUCKNOW**.

65) An example of narcotic drug is **Coca and hemp**.

66) Schedule E Drugs should be labeled with the word **Keep away from children**.

67) No licenses will be issued for repelling **Schedule X** drugs.

68) Drug retail sale licenses are issued by **Drug controller officer/ D.I**.

69) The magic remedies act was passed in the year **1955**.

70) Quantities of sample taken for analysis should not be less than **3-4 samples.**

71) The committee that advises the DTAB and various governments is **Drug consultative committee.**

72) All shops and establishments required to be registered with **Shop and establishment act, 1947.**

73) Talismans, mantras, kavachas come under **Drug and magic remedies act, 1955.**

74) Life period of drug is deal with **schedule P**

75) The poisons Act was passed in the year **1919.**

76) Symbol NR, in red is displayed in the labels of **Narcotic drugs and psychotropic drugs.**

77) Narcotic drug and psychotropic substance act came into force on **1985**.

78) A person who falsely claims to be a registered pharmacist is fined **rupees 500/-** On first conviction and ***1000*** and **6 month imprisonment** on subsequent conviction.

79) According to ER 91, period of training after completing the course of diploma in pharmacy is **500 hours.**

80) Schedule J consists of list of **diseases or aliments which a drug may not to prevent or cure.**

81) Good manufacturing process was established in Schedule **M.**

82) **Jaisukh lal Hathi** was the chairman of Hathi Committee.

83) Sale of **schedule X** drugs are governed by the special provisions.

84) Drug controller of India is the **Executive** member of PCI.

85) A drug which is imported in the name of another drug is termed as **spurious drug.**

86) Full form of MAPE is **Maximum allowable post manufacturing expenses.**

87) Code of pharmaceutical ethics is formulated by **PCI**.

88) Report of drugs enquiry committee was submitted in the **1931** year.

89) A place where drugs are compounded and dispensed are termed as **Pharmacy**.

90) Opium to be used for manufacturing of medicines supplied from **govt. opium commissioner** only.

91) Tests on **opium** are carried out at Indian pharmacopoeia laboratory.

92) Minimum area recommended for parenteral preparation is **schedule X**.

93) Drug (price control) order was enforced in the year **1966**.

94) **Excise** duty is payable on alcoholic preparations which are exported from India.

95) MTP act was passed in year **1971** and extends to whole of India except J **& K**.

**Question no. 2. Define the terms. Each question carries one mark.**

**1) Cosmetic –** Articles meant to be rubbed, poured, sprinkled or sprayed on any part of the human body for cleansing, beautifying, promoting attractiveness or altering appearance.

**2) Spurious drug -** It includes a drug which is imported under a name which belongs to another drug, if the label or containers bears the name of an individual or company purposing to be the manufacture of the drug which is fictitious or does not exist.

**3) New drug-** All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquito.

**4) Addict-** A person addicted to any narcotic drug or psychotropic substance.

**5) Coca Leaf-** Leaves of any plant of genus erythroxylon excepting those from which cocaine, ecgonine and other ecgonine alkaloids have been removed or any mixture, with or without neutral materials, containing more than 0.1% cocaine.

**6) Magic Remedy-** Talismans, mantras, kavachas and like substances or charms purposing to posses miraculous powers of prevention or cure of disease or of affecting or altering any function of the human or animal bodies.

**7) Registered Pharmacist -** A person whose name for the time being is entered in the register of pharmacists of the state in which he is for the time being residing or carrying on his profession or business of pharmacy.

**8) Central Register-** Central register means the register of pharmacist maintained by the central council.

**9) Advertisement** Include all notices, circulars, labels, wrappers or other document and all announcements made orally or by means of producing or transmitting light, sound or smoke.

**10) Cannabis -** Means i) Charas i.e. the separated resin, whether crude or purified, obtained from the cannabis plant. It also includes concentrated preparation and resin known as hashish oil or liquid hashish.
ii) Ganja i.e. the flowering or fruiting tops of the cannabis plant.
iii) Any mixture, with or without any neutral material, or any of the above forms or cannabis or any drink prepared there from.

**11) Drug Adulteration -** A drug is said to be adulterated if it consists, in whole or in part of any filthy, putrid or decomposed substance, A drug is also adulterated if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filthy or it may be injurious to health or any substance has been mixed to reduce its quality or strength and to increase activity.

**12) Opium-** Coagulated juice of opium poppy or any other species of papaverum from which opium or any phenanthrene alkaloid can be extracted and which may be declard to be opium poppy by notification by the central government or any mixture of opium poppy, with or without neutral materials containing more than 0.2% morphine**.**

**13) Drug Store-** Premises licensed for sale of drugs which may or may not have a qualified person.

**14) Pharmacy-** Premises licensed for the retail sale of drug which have a qualified person and indulge in the compounding of drugs.

**15) Repackaging of Drugs-** Process of breaking up any drug from a bulk container into small packages and labeling of these packages with a view to their sale and distribution.

**16) Patients and Proprietary Medicines-** Formulation containing ingredients according to formula of a books listed into Drug and Cosmetic Act excluding medicines for parenteral use.

**17) Ceiling price-** Ceiling price means a fixed price by the government for scheduled formulations.

**18) Qualified Persons-** Person holding degree or diploma in pharmacy or pharmaceutical chemistry or registered as pharmacists under the pharmacy act or having not less than 4 year experience of dispensing, considered adequate by the licensing authorities or persons who were approved as qualified persons before 13.12.1969.

**21) Poisons-** Substances notified as poisons under the poisons act 1919. A poison is a substance that on cause serious illness if you eat or drink it.

**22) Bonded Laboratory-** means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparation containing alcohol, opium, Indian hemp and other narcotic drug on which duty is not paid.

**23) Import-** Import means bringing goods into India from a place outside India, and importer in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer.

**24) Ethics-** The word ethics originates from a greek word **Ethikos** meaning custom or character. The current dictionaries define as relating to morals, the science of morals, branch of philosphy concerened with human being and character.

**25) Chemist and Druggist-** Premises licensed for the sale of drugs which have a qualified person but wherein drugs are not compounded**.**

**26) Govt. Analyst -** Person appointed for the analysis and testing of samples of drug and cosmetics under section 20 of drug and cosmetic act.

**27) RMP-** Registered medical practitioner means a person who posses any recognized medical qualification as defined under the Indian medical council act and whose name has been entered in a state medical register.

**28) Narcotic drug-** Narcotic drug means a substance which is coca leaf or coca derivative or opium or derivative of opium, or Indian hemp and includes all manufactured drugs .

**29) Toilet Preparation-** Any preparations which is intended for use in the toilet for human body or any substance intended to clean, improve, or alter the complexion, hair, skin, or teeth and include deodorants and perfumes.

**30) Formulation-** The formulation have been defined as medicines containing one or more bulk drug or drugs for diagnosis, treatment, prevention of disease in human being or animals and for internal or external use excluding ayurvedic Siddha, Unani and homeopathic medicines.

**Section-B** **3 x 5 = 15**

**Attempt any five questions. Each question carries three marks.**

**Question no. 1** What is the main objective of poison act?

**Question no. 2** What do you mean by manufacture in bond?

**Question no. 3** What is constitution of State Pharmacy Council?

**Question no. 4** What advertisements are prohibited under Drugs and Magic Remedies Act 1954?

**Question no. 5** What are loan and repacking licenses?

**Question no. 6** What is the role of pharmacist in handling of prescription?

**Question no. 7** What is the qualification of Government Analyst?

**Question no. 8** State salient features of labeling of schedule C drugs.

**Question no. 9** Define misbranded drugs.

**Question no. 10** What is the power of drug inspector?

**Question no. 11** What do you mean by good manufacturing practices?

.**Question no. 12** Explain how and why Pharmacy council of India can disaffiliate education Institutions.

**Question no. 13** Discuss why morphine is allowed to be manufactured and marketed while their acetyl derivative is totally prohibited drug.

**Question no. 14** Discuss the specific condition required for granting a licence for the manufacture of alcoholic medicinal preparation.

**Question No. 01 What is the main objective of poison act?**

**Answer.** The Poisons Act, was passed on 3 September, 1919 with the main object of consolidating and amending the laws regulating the import, possession and sale of poisons. The Act of 1919 replaced the Poisons Act of 1904 which was intentionally limited in its scope to restrict interference with legitimate industries as much as possible but it was proved by experience that the control afforded by the act of 1904 over the traffic in poisons was inadequate. So, the act of 1919 was passed with the object of tightening the control over traffic in poisons. According to this act, Central Government is authorized to regulate import of poisons and State Governments are authorized to regulate the possession and sale of poisons, within their respective areas.

**Question No. 02 What do you mean by manufacture in bond?**

**Answer:** Manufacture in bonding is the manufacture of preparations containing alcohol for which licence must be obtained. Preparations are deemed to be manufactured in bond when they are manufactured in a premises,

licensed or approved for this purpose and on which excise duty is not paid until the finished products are removed from the licensed premises. At least 2 months before the proposed date of commencement of the manufacture the application for the licence should be submitted.

**Question No. 03. What is constitution of State Pharmacy Council?**

**Answer.** The Pharmacy Act, 1948 provides for the constitution of a State Pharmacy Council in each State. The State Pharmacy Council has the following constitutions:

**Elected members:**

1. Six members elected amongst themselves by Registered Pharmacist of the State.
2. One member elected by the medical council of the State from amongst its members.

**Nominated Members:**

1. Five members nominated by the State Government of whom at least three should possess a degree or diploma in Pharmacy or Pharmaceutical chemistry or should be Registered Pharmacist.

**Ex-officio members:**

1. Chief administrative medical officer of the State.
2. Officer in-charge of Drugs control Administration of the State.
3. Government analyst of the State or where there is more than one analyst, from them one as may be appointed by the State Government.

The President and vice president of the council are elected from amongst themselves for a term of five years. The council usually appoints Registrar and other necessary officers and staff as may be required to carry out its functions.

**Question No. 04. What advertisements are prohibited under drugs and magic remedies act 1954?**

**Answer:** The following classes or advertisements are prohibited to be made under the act:

1) **Advertisements, relating to drugs, which are used in the following ailments or conditions**:

a) For the procurement of miscarriage or prevention of conception in women.

b) For the correction of menstrual disorders in women.

c) For the maintenance or improvement of capacity of human beings for sexual pleasure.

d) The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in schedule J of the Drugs and cosmetics Rules, 1945.

2) Advertisements, which directly or indirectly gives false impression regarding the true character of the drug.

3) Advertisements relating to magic remedies claming their efficacy for any of the conditions outlined in (1) by persons, who support to carry on the profession of administering magic remedies.

**Question No. 05 What are loan and repacking licences?**

**Answer: Loan licences:** A loan licence is issued to a person who does not have his own premises and facilities for the manufacture of drugs but who intends to have his drugs manufactured at the premises of another person. Loan licence can be granted only for drugs other than those specified in Schedule X. Applications for grant of loan licence should be supported by documentary consent of the licensee whose facilities are to be availed for the manufacture. The licensee is required to test each batch of raw materials and finished goods and maintain records of the tests for at least 5 years from the date of manufacture (2 years in case of drugs with an expiry date).

**Repacking Licences:** A repacking licence is required for the purpose of breaking up any drug other than those specified in Schedules C and $C_1$, from a bulk container into small packages with a view to its sale and distribution.

**Question No. 06 What is the role of pharmacist in handling of prescription?**

**Answer:** Role of pharmacist in handling of prescriptions is as follows:

1) Prescription should not be discussed with patients or others regarding the merits and demerits of their therapeutic efficiency.

2) After receiving the prescriptions, a pharmacist should not even show any expression of astonishment, as such thing may cause anxiety in patients and may even shake faith in their physician.

3) No addition, omission, or substitution of ingredients in a prescription should be made without the consent of prescriber.

4) In case of any obvious error in the prescription, it should be referred back to the prescriber for necessary correction.

5) A pharmacist should not recommend any particular prescriber, unless he is specially asked to do so.

**Question No. 07 What is the qualification of Government Analyst?**

**Answer:** A person to be appointed as a Government Analyst should have no financial interest in the import, manufacturer or sale of the drugs or cosmetics and should possess the following qualifications:

1) A graduate in medicine or science or pharmacy or pharmaceutical chemistry from a recognized University, with not less than 5 years experience in the testing of drugs; or

2) A post graduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized University with not less than 3 years experience; or

3) Associateship Diploma from the Institution of Chemists (India) with 'Analysis of drugs and Pharmaceuticals' with not less than 3 years experience in the testing of drugs in a laboratory under the control of a Government Analyst, head of an Institution or testing laboratory approved for the purpose by the appointing authority.

**Question No. 08 State salient features of labeling of schedule C drugs.**

**Answer:** The following information is required in case of Schedule C drugs:

1) Proper name of the substance in addition to any patent or proprietary name.

2) Statement of potency in units whenever required by the rules.

3) Name and address of the manufacturer of the final product.

4) Date of manufacture & expiry date.

5) Date of expiry whenever prescribed.

6) Where a test for maximum toxicity is prescribed, a statement that the drug passed the test.

7) Nature and percentage of antiseptic added, if any.

8) Precautions necessary for preserving the properties of the drug.

9) Licence No. under which manufactured or imported.

10) Batch No. or Lot No.

**Question No. 09. Define misbranded drugs.**

**Answer. -** A drug is termed as misbranded.

i) If it is so colored, coated, powdered or polished or if it is made to appear of better or greater therapeutic effect than it really is.

ii) If it is not labeled in prescribed manner.

iii) If its label, container or package bears any statement, design or device which makes any false claim for the drug or misleading in any way.

**Question No. 10. What is the power of drug inspector?**

**Answer:**The Drug Inspector has been empowered to carry out the following functions:

1) Inspection of premises where any drug or cosmetic is being manufactured, sold, stocked or offered for sale and the means employed for standardizing and testing the drugs or cosmetics.

2) Taking samples of any drug or cosmetic which is being manufactured, being sold, is stocked or exhibited or offered for sale.

3) Taking samples of drug and cosmetic from any person conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

4) Examine any record, register, document or any other material object with any person in any place mentioned above and seize the same if it is likely to furnish the evidence of an offence.

**Question No. 11. What do you mean by good manufacturing practices?**

**Answer.** Good Manufacturing Practice is a set of regulations, codes, and guidelines for the manufacture of drug substances and drug products, medical devices, in vivo and in vitro diagnostic products, and food products.

**General requirements are:**

**1)** The factory should be located in a sanitary place & well constructed with hygienic condition..

2) Purified Water should be used for all operations except washing and cleaning operations where potable water may be used.

3) The manufacture shall provide adequate facilities for first aid medical inspection of workers at the time of employment and periodic check up thereafter at least once a year.

4) In order to avoid the risk of corss-contamination, separate dedicated and selfcontained facilities shall be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live micro-organisms.

5) All works shall be free from contagious or obnoxious disease.

**Question No. 12. Explain how and why Pharmacy council of India can disaffiliate education Institutions.**

**Answer:** An institution proposing to conduct course of study or holding an examination for pharmacist has to apply to PCI for approval of the course or examination. After receiving such official application PCI can depute its inspector to visit the institution. If the PCI is satisfied with the report of inspectors, it may accord approval and the said course or examination will be claimed to be approved for qualifying for registration as Pharmacist and approvals are published in the Gazette. If the Executive Committee reports to the PCI that an institution holding a course or examination does not continue to be in conformity with the Education Regulation, the PCI may issue notice of its intention to withdraw its approval. The said institution can make a representation within 3 months to PCI through State Government. PCI then decides to either continue with approval or withdraw it.

**Question No. 13. Discuss why morphine is allowed to be manufactured and marketed while their acetyl derivative is totally prohibited drug.**

**Answer.** Morphine acts as anesthetic without decreasing consciousness and it is one of the most powerful analgesic known. It is also used in severe pain. Acetyl derivative (heroin) is highly addictive drug, being twice as active as morphine. Medical complication including insomnia, constipation, lung complication and poor health, depression of heroin has make its an totally prohibited.

**Question No. 14. Discuss the specific conditions required for granting a licence for the manufacture of alcoholic medicinal preparations.**

**Answer.** Every person desiring to manufacture Medicinal and Toilet preparation containing alcohol or other narcotic substances is required to obtain a licence. The application for the grant of licence should be submitted in the prescribed form together with prescribed fee, at least 2 months before the proposed date of the commencement of manufacture and should specify:

1) The name and address of the applicant.

2) Name and address of the place and the site on which the Bonded or Non-bonded Laboratory is situated or to be constructed.

3) The amount of capital proposed to be invested.

4) Approximate date from which the applicant desire to start the manufacture if the required licence is granted.

5) The number and full description of the vats, stills and other permanent apparatus and machinery which the applicant wishes to set up.

6) The maximum quantity of alcohol and alcoholic content in unfinished and finished preparations are likely to remain in laboratory at any time.

7) Site and elevation plans of laboratory building or buildings showing the location of the different rooms with doors and windows there in.

On receipt of such applications the licensing authority enquires about the qualifications and experience of the technical persons and the equipments of the bonded or non-bonded laboratories. After satisfying that the applicant is eligible for the issue of a licence, the licensing authority (Excise Commissioner) shall issue a licence.

**Section-C** **5 x 5 = 25**

**Attempt any five questions. Each question carries five marks.**

**Question no. 01** Define charas and prepared opium.

**Question no. 02** Explain what records should a person licenced to manufacture drugs necessarily to maintain.

**Question no. 03** Explain whether a drug inspector can raid a food godown.

**Question no. 04** Differentiate between spurious cosmetic drugs and spurious preparations.

**Question no. 05** What are the labeling requirements of samples of drugs meant for free distribution to doctors?

**Question no. 06** Explain whether homeopathic drugs may be imported into India without any licence.

**Question no. 07** Why homeopathic drugs can be prepared as parenteral products.

**Question no. 08**Differentiate between Narcotic drugs and Psychotropic substances.

**Question no. 09** Discuss condition when a pharmacist can be penalized.

**Question No. 01. Define charas and prepared opium.**

**Answer. Charas:** The separated resin in crude or purified state obtained from the cannabis plant and also includes concentrated preparations and resin known as hashish oil or liquid hashish.

**Prepared Opium:** Opium that is any product of opium by series of operations designed to transform opium into an extract suitable for smoking and any residue left after it is smoked.

**Question No.02. Explain what records should a person licenced to manufacture drugs necessarily maintain.**

**Answer.** (i) The licensed premises must conform to the requirements of goods manufacturing practices specified in schedule M.

(ii) The licensee must provide adequate arrangements for testing the strength and quality of drugs in the licensed premises and the testing unit should be separate from the manufacturing unit.

(iii) The licensee must have adequate facilities for the storage of the drug manufactured by him so that their properties would be preserved.

(iv) Records of the details relating to the manufacture and testing of each batch of drugs should be maintained. The records for those drugs which have date of expiry should be preserved for a period of at least 2 year from the date of their expiry and other drugs for a period of 5 years from the date of their manufacture.

(v) The licensee must report to the licensing authority any changes in the staff employed for the manufacturer of drugs and also any material changes in the plant or premise used for the manufacturer since the date of last inspection.

**Question No. 03. Explain whether a drug inspector can raid a food godown.**

**Answer.** No, a **drug** inspector cannot raid a food godown. He has authority only to raid the godown or shops related to medicine or drug food product do not come this category. To raid the food godown, food inspector is authorized by state govt.

**Question No. 04. Differentiate between spurious drugs and spurious Cosmetics.**

**Answer.**

| S. No | Spurious Drugs | Spurious Cosmetics |
|---|---|---|
| **1.** | A drug is called spurious drug If it is imported under a name which belongs to another drug; or | A preparation is called spurious If it is imported under the name which belongs to another cosmetic; or |
| **2.** | If it is an imitation of , or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or containing the name of another drug unless it is plainly and | If it is an imitation of, a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or containing the name of another cosmetic, |

| | | |
|---|---|---|
| | conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or | unless it is plainly or conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or |
| **3.** | If the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or | If the label or the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist; or |
| **4.** | If it purports to be the product of a manufacturer of whom it is not truly a product. | If it purports to be the product of a manufacturer of whom it is not truly a product. |

**Question No. 05. What are the labeling requirements of samples of drugs meant for free distribution to doctors?**

**Answer.** The containers of all the drugs including patent or proprietary medicine are to be labeled in accordance with the Drug and Cosmetic Rules 1945. The following particulars should be either printed or written in indelible ink and should appear in conspicuous manner on the label of the inner most container of any drug or other covering in which the container is packed:-

1) The name of drug.
2) A correct statement of the net contents in terms of weight, measure, volume, number of units of activity, as the case may be, are expressed in metric system.
3) The name and address of the manufacture. Manufacturing licence number, or Mfg. Lic. No or M. L.
4) The content of active ingredients:
5) A distinctive batch number preceded by 'Bathch No'or 'Lot No'.
6) Expiry particulars, if any.
7) Information related to storage or manner or use.
8) Precautionary information related to care in handling, use, distribution etc.
9) General information such as 'Physician's sample, not for sale' etc.

**Question No. 06. Explain whether homeopathic drugs may be imported into India without any licence.**

**Answer.** The homeopathic drugs may be, in general, imported into India without any licence for the purposes of import they are classes with such allopathic drugs for the import of which no licence is necessary. However, new homeopathic medicines (meaning medicines not specified in the homeopathic pharmacopoeias of U. S. A and U. K. or not recognized as efficacious in authoritative homeopathic literature under recommended conditions of use) cannot be imported without the permission of the Licensing Authority. For obtaining such permission the importer has to furnish to the Licensing Authority evidence, including the minimum proving

carried out with it, as may be required for assessing efficacy of the medicine. All imported homeopathic medicines should be labeled and packed in accordance with the rule.

**Question No. 07. Why homeopathic drugs can be prepared as parenteral products.**

**Answer. The advantages of homeopathic medicines:**

1) **No change in the homeopathic substances**: Avoiding the gastrointestinal tract by means of injection avoids any change in the homeopathic medicine through the action of either enzymes or the gastric juice.

2) **No viral or microbial risks**: Since every substance for injection in the EU has to meet the sterility requirements of the official pharmacopoeia as stated in the Parenterals monograph of Pharm. Eur. 1997, a risk of infection from this dosage form can largely be excluded.

3) **Better patient compliance**. An injection is generally given only by the doctor or therapist.

4) **Improved action through injection**: When giving injections into acupuncture points or into Head's zones (segmental therapy) the therapist is exploiting the fact that each segment or each acupuncture point is connected to a particular organ or a region of tissue via the appropriate meridian. Injection here, targets exactly the connected organ.

It is interesting in this connection that 61.2% of the doctors surveyed said that the homeopathic injection can readily be combined with other types of treatment (e.g. physiotherapy and/or allopathic medication).

**Question No. 08. Differentiate between Narcotic drugs and Psychotropic substances.**

**Answer. Narcotic drug:** Narcotic drug means coca leaf, cannabis (hemp), opium, poppy straw and include all manufactured drugs. It also include any substance capable of causing or producing dependence, tolerance and withdrawal syndromes and which the Central Government may by notification in the Official Gazette, declare to be narcotic drug or narcotic.

**Psychotropic substances:** Psychotropic substances means any substance, natural or synthetic, or any natural material or any salt or preparation of such substance or material included in the list of psychotropic substances specified in the Schedule.

**Question No. 09. Discuss condition when a pharmacist can be penalized.**

**Answer.** The following are considered to be offences under the Act:

**1. Penalty for falsely claiming to be Registered Pharmacist:** If any person whose name is not entered in the register, falsely claims to be a Registered Pharmacist or uses in connection with his name or title any words or letters is so entered, he shall be punishable on first conviction with fine which may extend to five hundred rupees and on any subsequent conviction with imprisonment extending to six months or fine up to thousand rupees or both. If a person who is a registered pharmacist in another state and who at the time of making claims

to registration in the state has filed an application for registration shall not be deemed to be guilty of the offence.

**2. Dispensing by unregistered persons:** Only registered pharmacist persons can compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner. Whoever contravence this provision is punishable with imprisonment up to six months or with fine up to one thousand rupees or with both.

**3. Failure to surrender certificate of registration:** If any person whose name has been removed from the register and who fails to surrender his certificate of registration to registrar without sufficient reason is liable to a fine which may extend to fifty rupees.

**4. Obstructing State Pharmacy Council Inspectors:** Any person, who willfully obstructs an inspector of the State Pharmacy Council, may be punished with imprisonment up to 6 months or fine up to one thousand rupees or both.

**Section-D** **3X10=30**

**Attempt two questions. Each question carries ten marks.**

**Question no. 1** Discuss the construction, function and power of Drug Technical Advisory Board.

**Question no. 2** Give detail of Pharmacy Council of India and Education Regulation laid by it.

**Question no. 3** How the prices of drugs in bulk and of the drug formulation calculated under the Drug Price Control order?

**Question no. 4** Write short note on (a) Poison Act (b) Medical termination of pregnancy act.

**Question no. 5** Discuss in detail code of pharmaceutical ethics.

**Question no. 6** Explain the different licence issued and their conditions required as per Drug and Cosmetics Act, for retail sale of drugs.

**Question No. 01. Discuss the construction, function and power of Drug Technical Advisory Board.**

**Answer.** DTAB (Drug Technical Advisory Board) is constituted by the Central Government to advise the central and State Governments on technical matters.

Constitutions: - It consist of 18 members which are –

**Ex-officio members –**

i) Director General of Health Services (Chairman).
ii) Drug Controller of India.
iii) Director, Central Drug Laboratory, Calcutta.
iv) Director, Central Research Institute, Kasauli.
v) Director, Indian Veterinary Research Institute, Izatnagar.
vi) President, Medical Council of India (MCI).
vii) Director, Central Drug Research Institute, Luckhnow.

**Nominated Members: -**

i) Two persons nominated by the Central Government from amongst persons who are incharge of drugs centers in States.

ii) One person from the pharmaceutical Industry, nominated by the Central, Government.

iii) Two Government Analysts, nominated by the Central Government.

**Elected Members: -**

i) A teacher in Pharmacy or Pharmaceutical chemistry or Pharmacognosy from the staff of an Indian University or College, elected by the Executive committee or the Pharmacy Council of India.

ii) A teacher in medicine or therapeutics on the staff of an Indian university or an affiliated college, elected by the Executive Committee of the Medical Council of India.

iii) One Pharmacologist elected by the governing body of the Indian council of medical research.

iv) One person elected by the council of the Central Medical Association.

v) One person to be elected by the council of the Indian Pharmaceutical Association (IPA).

The nominated and elected members hold the office for 3 years but are eligible for re-nomination or re-election. Election Governments appoints a secretary and other staff to the board. Education Regulation take effect in a State from the date notified by the State Government in the Official Gazette.

**Question No. 02. Give detail of Pharmacy Council of India and Education Regulation laid by it.**

**Answer. Construction:** The first Pharmacy Council of India was constituted in 1949. PCI & constituted by Central Government every five years.

**i) Elected Members:**

a) Six members, at least one teacher each of Pharmacy, Pharmaceutical chemistry, Pharmacology and Pharmacognosy elected by U.G.C. from teaching staff of an Indian University of College granting a degree or Diploma in Pharmacy.

b) One member, elected by the Medical council of India (MCI) from amongst its members.

c) One member, elected by each State Pharmacy Council who shall be a Registered Pharmacist.

**ii) Nominated Members:**

a) Six members, nominated by the Central Government, including at least four persons having Degree or Diploma in Pharmacy and engaged in the Practice of Pharmacy or Pharmaceutical chemistry.

b) One representative each of University Grants Commission and All India Council for Technical Education.

c) One Registered Pharmacist to represent each State nominated by the State Government/Union Territory Administration.

**iii) Ex-Officio Members:**

a) Director General of Health Services.
b) Director of Central Drugs Laboratory (CDL)
c) The Drugs Controller of India.

The President and Vice President of the PCI are elected by its members from amongst themselves for a term of five years.

**The council appoints:**

a) A Registrar who acts as it secretary.
b) Other officers and servants for carrying out its functions.
c) The Executive Committee of the PCI consisting of the President (Chairman of the Committee) and Vice President and five other members elected by the Central Council from amongst its members.

**Functions of PCI -**

a) To prescribe the minimum standards of education required for qualification as a Pharmacist.
b) To regulate the minimum educational standards by inspecting the institutions.
c) To recognize qualification granted outside the territory to which the Pharmacy Act, 1948 extends, for the purpose of qualifying for registration.
d) To compile and maintain a Central Register for Pharmacists containing names of all registered persons.
e) Any other function required for completion of objectives of Pharmacy Act, 1948.

**Education Regulations (ER)**

The pharmacy council of India has laid down certain minimum standards of education required for qualification as Pharmacist. These standards are known as Education Regulations and it prescribe.

i) Minimum educational qualification required for admission to the course of Pharmacy.
ii) Duration of course of study and training.
iii) Nature and period of practical training to be undertaken after the completion of regular course.
iv) Subjects of examination and the standards to be attained there in for qualification.
v) Minimum facilities required to be provided by an institution for the conduct of course examination and practical training.
vi) Conditions to be fulfilled by the authorities holding approved examinations.

**Main features of Education Regulations-91**

According to ER-91 a candidate has to undergo practical training after having appeared in Diploma in Pharmacy Part II examination in one or more following institutions:

i) Government hospitals/dispensaries.
ii) Other hospitals/ dispensaries recognized by PCI.

iii) Licensed Pharmacy, chemists and druggists shop.

iv) Licensed drug manufacturing units.

Practical should be for a minimum of 500 hours spread over a period of not less than three months out of which not less than 250 hours must be devoted to actual dispensing of prescriptions. The Education Regulations are approved by Central Government and also published in official gazette, in consultation with the State Council at any time after it is constituted.

**Question No. 03. How the prices of drugs in bulk and of the drug formulation calculated under the drug price control order?**

**Answer. Drugs (price control) order, 1995: -** The drug (price control) order, 1995 was passed by the central government. The order extends to the whole of India and replaces the drugs order, 1987. It is effective from the date of its publication in the Official Gazette. The drugs (Price Control) Order, 1995 was passed by the Central Government with the following objectives:

(a) To regulate the equitable distribution of essential bulk drugs.

(b) To fix the maximum sale prices of essential bulk drugs and drug formulation.

**Sale Prices of bulk drugs: -** The government may fix, the maximum sale price at which any bulk drug specified in the First schedule can be sold from time to time, by notification in the Official Gazette. No person can sell a bulk drug at a price exceeding the fixed price plus local taxes, if Any manufacturer who commences the production of any bulk drug specified in the First schedule, after the commencement of this order, is required to furnish the necessary details in form I within fifteen days of the commencement of the production of such bulk drug to the Government. The Government may then, after making necessary inquiries, fix the maximum sale price of the bulk drug by notification in the Official Gazette.

Any manufacturer, who desire revision of the maximum sale price of a bulk drug should make an application to the Government in form I. the Government, shall then, within four months from the date of receipt of the complete information, fix a revised price for such bulk drug or reject the application for reasons to be recorded in writing.

Every manufacturer of a scheduled bulk drug or a non- scheduled bulk drug has to submit to the Government a list of all bulk drugs produced by him indicating the details of the cost of each such bulk drug within thirty days of the commencement of the order and by $30^{th}$ September thereafter, every year.

The government may, in public interest, fix or revise the price of any non-scheduled bulk drug and the manufacturer or importer such bulk drug shall not sell the same at a price exceeding the price so fixed or revised, within fifteen days of receipt of the order.

**Calculation of retail price of Formulations:** The retail price of a formulation can be calculated in accordance with the following formula:

**R.P. = (M.C. + C.C. + P.M. + P.C.) (1+MAPE/100)+E.D.**

Where,

**R.P. -** means retail price;

**M.C. -** means material cost and includes the cost of drugs and other pharmaceutical aids used.

**C.C. -** means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

**P.M. -** means cost of the packing material including process loss;

**P.C. -** means packing charges;

**M.A.P.E**. - Means all cost incurred by manufacturer from the stage of ex-factory cost to retailing and includes trade margin for the manufacturer and it shall not exceed 100% for indigenously manufactured scheduled formulations.

**E.D. -** Means Excise duty.

Provided that in the case of an imported formulation, the landed cost shall from the basic for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty per cent of the landed cost. For imported formulations, the retail prices may be fixed on the basis of landed costs and shall not exceed 50% of the landed cost.

**Price and Price List: -** Every manufacturer, importer or distributor of a formulation intended for sale is required to display in indelible print mark, on the label of container of formulation and the minimum pack thereof, the retail price of that formulation. The retail price should be indicated as "Retail price not to exceed Rupees….. Local taxes extra". In case of non-scheduled formulation offered for sale the retail price should be indicated as "Maximum retail price Rupees ….. Inclusive of all taxes".

**Question No. 04. Write short note on (a) Poison Act (b) Medical termination of pregnancy act.**

**Answer.** Poisons Act was passed on 3rd Sept. 1919 with a view to control the import, possession and sale of poisons. For the purposes of the Act, all substances, specified as poisons in notification issued under the Act, are to be deemed as poisons.

**Import of Poisons: -** The import of poisons is permitted only by persons who have been granted license for this purpose by Central Government and such person import poisons in accordance with the conditions.

**Possession and Sale of Poisons or Provisions of the Act: -** The State Govt. may make rules in order to regulate the possession and sale of poisons. Such rules may provide for –

i) The grant of licenses for the possession and sale of any specified class of poisons and fixing of the fees to be paid for grant of such licences.
ii) The classes of persons to whom the licences for the permission and sale of poisons are to be granted.
iii) The categories of persons to whom the poisons may be sold.

iv) Maintenance of a sale registers.

v) The safe custody of poisons and labeling of the vessels, packages or coverings, etc. in which poisons are sold or stored for sale.

vi) Inspection and examination of any such poison possessed by a person for sale.

**Penalties for offences under the Act:** Anyone, who either imports, possesses or sells any poison, except as provided under the Act, is punishable with:

i) Imprisonment up to 3 months or a fine up to Rs. 500/- or both on first time.

ii) Imprisonment up to 6 months or a fine up to Rs. 1000/- or both on any subsequent conviction.

iii) Anyone, who possesses any poison, whose possession has been forbidden by the state govt. shall be liable to imprisonment, which may extend to one year or with a fine up to Rs. 1000/- or both.

**Exemptions:** The provisions of the act shall not apply to anything done in good faith by a medical or veterinary practitioner while discharging his professional duties.

**Ans.4. (b) Medical Termination of Pregnancy Act, 1971:-** The Medical Termination of Pregnancy Act was passed by the parliament in 1971 with view to provide for termination of pregnancy by Registered Medical Practitioners for bonafide medical reasons. The Act extends to whole of India except the state of Jammu and Kashmir due to the following reasons:

i) Legal abortions were difficult at that time and many were being carried out illegally under unhygienic or unsafe conditions resulting in harm to health or life of women.

ii) As a population control measures.

**Provisions of the Act:**

The Medical Termination of Pregnancy Act provides that pregnancies of women may be terminated by Registered Medical Practitioners under the following circumstances:

i) Pregnancies of woman, 18 years of age or more, with their consent or in case of woman who less than 18 years of age or are lunatics, with the written consent of their guardians.

ii) A pregnancy which is not more than 12 weeks old and the medical practitioner is of the opinion that its continuance is a grave danger to the life of the woman or to her physical and mental health or the child to be born would be seriously handicapped due to physical or mental abnormalities.

iii) A pregnancy which is more than 12 weeks but not more than 20 weeks old, provided that not less than two registered medical practitioners are of such a opinion.

iv) A pregnancy of any duration provided that the medical practitioner of the opinion that such termination is immediately necessary to save the life of the pregnant woman.

v) A pregnancy which is alleged to have been caused due to rape or due to failure of a contraceptive device used by a woman or her husband for family planning purposes.

vi) In determining health hazards of pregnancy, the women's actual condition in the foreseeable future may be taken into account. The pregnancy of a woman may be terminated by a RMP only at a hospital established or maintained by the Government or a place approved by it for the purpose.

**Requirement for Places approved for Termination of pregnancy:**

Places approved for termination of pregnancy should have:

i) An operation table with facilities for gynaecological or abdominal surgery.
ii) Anesthetic equipment, resuscitation equipment and sterilization equipment.
iii) Drugs and parenteral fluids for emergency use.
iv) Qualified medical personnel.

The application for the approval of a place for the termination of pregnancy should be addressed to the Chief Medical Officer of the District concerned, who shall inspect such place and if satisfied, shall recommend the Government to approve the place and issue a certificate of approval. The certificate must be conspicuously displayed at the place so that it is easily visible to persons visiting the place. The certificate can be cancelled or suspended if the prescribed facilities are not maintained and termination of pregnancy at such place cannot be made under safe and hygienic conditions.

**Requirement of experience or training for a RMP to terminate pregnancy:**

Any RMP having the following experience/training in the practice of gynaecology and obstetrics can terminate pregnancy under the Act:

i) If the RMP was registered in a State Medical Register before the commencement of this Act:
   a) An experience in the practice of gynaecology and obstetrics for not less than three years.

ii) If the RMP was registered on or after the commencement of this Act:
   a) Six months of house surgery in gynaecology and obstetrics.
   b) In case, he has not done any such house surgery, an experience in the practice of gynaecology and obstetrics in any hospital for not less than one year.
   c) Experience by way of assistance given by the person to a RMP in the performance of twenty-five cases of medical termination of pregnancy in a hospital established or maintained, or a training institute approved for this purpose, by the Government.

**Offences and penalties:** The termination of pregnancy by a person who is not a Registered Medical Practitioner is punishable offence under the Indian Penal Code. Anyone who fail to comply with rules made under the Act or contravenes them may be fined upto Rs. 1,000/-.

**Question No. 05. Discuss in detail code of pharmaceutical ethics.**

**Answer.** The code of Ethics, framed by PCI has been meant to guide the Indian Pharmacist as to how he should conduct himself in relation to himself, his patients, general public, co-professionals and members of the medical and other health professions.

**1) Pharmacist in relation to his job:**

**(a) Scope of pharmaceutical services:** A pharmacy should provide a good pharmaceutical services including supply of commonly required medicines and emergency supplies at all times without delay.

**(b) Conduct of Pharmacy:** The conditions in the pharmacy should be such that risk or error of accidental contamination in the preparation, dispensing and supply of medicines are avoided.

**(c) Handling of prescriptions:** Prescription should be received by a pharmacist without any discussion or comment over it, regarding the merits and demerits of its therapeutic efficacy. Any question on a prescription should be answered with every caution and care. A Pharmacist should not add, omit or substitute any ingredient or alter the composition of a prescription.

(d) **Handling of Drugs:** A pharmacist should always use drugs and medical preparations of standard quality and all possible care should be taken to dispense a prescription by correctly weighing and measuring all ingredient.

**(e) Apprentice Pharmacist:** Pharmacist in-charge should see that the trainees are given full facilities for their work and give them adequate knowledge for dispensing of drugs.

**2) Pharmacist in relation to his trade:**

**(a) Price structure:** Prices, charged from the customers, should be fair and in keeping with the quality and quantity of drug supplied and the labour and skills required in making it ready for use.

**(b) Fair trade practice:** A pharmacist should not indulge in cut-throat competitions like offering prizes or gifts or by charging lower prices for any drug, than those charged by the competitors.

**(c) Purchase of Drugs:** Drugs should always be purchased from genuine and reputable source.

**(d) Hawking of Drugs:** Hawking of drugs and medicines is not allowed. Self services are also avoided.

**(e) Advertising and Displays:** A pharmacist should not use any display material, either on the premises, in the press or elsewhere in connection with the sale of medicines or medical appliances.

**3) Pharmacist in relation to medical profession:**

**(a) Limitation of Professional Activity:** Pharmacist should not take any medical practice that is to diagnosing disease and prescribing medicine. In case of accidents and emergencies, a pharmacist may however render first aid to the victim.

**(b) Clandestine Arrangements:** No pharmacist should enter into any secrete arrangements or contract with physician, to offer him any commission or any advantage by recommending his dispensary or drug store. A pharmacist should never disclose any information to any third person.

**(c) Liaison with Public:** A pharmacist should always aware with the modern developments in Pharmacy and other allied sciences by regularly reading books, journals and magazines.

**4) Pharmacist in relation to his profession:**

**(a) Professional vigilance:** In addition to being a law-abiding citizen himself, a pharmacist should also make others fulfill the provisions of the pharmaceutical and others laws and regulations. He should also help to maintain fair name and traditions of pharmacy.

**(b) Law-abiding citizen:** A pharmacist, engaged in profession should have a fair knowledge of the laws of land.

**(c) Relationship with Professional Organizations:** A pharmacist should join and promote the activities of professional organizations.

**(d) Decorum and Propriety:** A pharmacist should not do anything which spoils the decorum and propriety of pharmaceutical profession.

**Question No. 06. Explain the different licence issued and their conditions required as per Drugs and Cosmetics Act, for retail sale of drugs.**

**Answer:** For the retail sale two types of license are issued, general and restricted. General licenses are granted to the persons who have premises for the business and who engage the services of a Qualified person to supervise the sale of drugs and do the compounding and dispensing. Licences for retail sale of drugs other than those specified in schedule C, C1 and X are issued in form 20, for drugs specified in schedule C, C1 excluding those specified in schedule X in form 21 and for schedule X drugs in form 20 F.

**Conditions:**

**1)** The licence should be displayed in a prominent place in a part of the premises open to the public.

The licensee should comply with the provisions of Drugs and Cosmetics Act and Rules thereunder in force.

**2)** Any change in the qualified staff in charge should be reported by the licensee to the licensing authority within one month.

**3)** Drugs should be purchased only from a duly licensed dealer or manufacturer.

**4)** Any change in the constitution of the licensed firm should be informed to the licensing authority within three months and in the mean time a fresh licence should be obtained in the name of the firm with the changed constitution.

**5)** Precautions prescribed by the licensing authority for the storage of schedule C and C1 drugs should be observed.

**6)** For the sale of additional categories of drugs listed in schedule C and C1 excluding X, the licensee must take prior permission of the licensing authority.

**Restricted licences:** The licences for the restricted sale of drugs other than those specified in schedule C, C1 and X and those specified in schedule C and C1 but not in schedule X are issued in the form 20A and 21A, respectively. It can be issued to:-

(1) Dealer or a person in respect of drugs whose sale does not require the supervision of a registered Pharmacist;

(2) Itinerant vendors in exceptional cases for bonafide travelling agents of firms dealing in drugs; or

(3) To a vendor who purchases drugs from a licensed dealer for distribution in sparsely populated areas where other channels of distribution of drugs are not available.

**Conditions for restricted licence:**

(a) The licensee must have adequate premises equipped with facilities for the proper storage of drugs to which the licence applies provided that this condition does not apply to vendors.

(b) The licence should be displayed in a prominent place in a part of the premises open to the public or should be kept on the person of vendor who shall produce the same on demand by an Inspector or other officer authorized by the State Government in this behalf.

(c) The licensee should comply with the provisions of the Drugs and Cosmetic Act and Rules thereunder in force.

(d) Drugs should be purchased only from a duly licensed dealer or manufacturer.

(e) The licensee can deal only in such drugs as can be sold without the supervision of a registered pharmacist.