Que 1 Solve any Eight of the following

a) Difference between Law & Ethics (1mark for each point, any 2 points)

Sr.no.	Law	Ethics
1	**Definition**- Rules of human conduct binding on all persons in a state.	**Definition**- Rules by which a profession regulates action & sets standards for all its members.
2	Law may prevent one from causing injury to another but it can not force him to help his neighbor in hours of need	Helping the neighbor is the function of ethics.
3	A law is something you must obey	Ethics is how society expects you to behave
4	Law deals with actions that are punishable	Ethics deals with right & wrong
5	Laws are written & approved documents	Ethics also written words but they are not carrying legal status.
6	If law is broken, a violator may be subjected to punishment, a fine or imprisonment.	If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges.

b)1mark for each)

Schedules	Contents
A	List of forms used for making applications for issuing licenses, granting licenses, sending memorandums etc.
B	Fees for test or analysis by the Central Drug laboratory or Govt. Analyst.

c) Misbranded Drugs: (2marks)

A drug shall be deemed to be misbranded

a) If it is so coloured, coated, powdered or polished that, damage is concealed or if it is made to appear of better or greater therapeutic value than it really is, or

b) If it is not labelled in the prescribed manner, or

c) If it's label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

d) Functions of Central Drug Laboratory (CDL) (1/2 mark for each point, any 4 points)

1) To analyze or test the samples of Drugs or Cosmetics sent to it by customs collector or the courts.

2) To carry on with the duties entrusted by the Central or State Govt.

3) In case of following drugs or classes of drugs functions of CDL are carried out Central Research Institute Kasauli & such functions are exercised by the Director of the said Institute

a) Sera

b) Vaccines

c) Toxins

d) Antigen

e) Solution of serum protein for injection.

f) Sterilized Surgical ligatures & suture

4) In case of following drugs or classes of drugs functions of CDL are carried out at Indian Veterinary Research Institute Izatnagar & such functions are exercised by the Director of the said Institute

a) Antisera

b) Vaccines

c) Toxoids

d) Diagnostic antigens for veterinary use

5) In case of condoms the functions of CDL is carried out at Central Indian Pharmacopoeia Laboratory Ghaziabad & such functions are exercised by the Director of the said Institute

6) The functions of the laboratory in respect of Homeopathic medicines shall be carried out at the Homeopathic Pharmacopoeia Laboratory Ghaziabad

e) Definition of cosmetics:- (2marks)

- It means any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or applied to any part of the human body, for cleansing, beautifying, promoting, attractiveness or altering the appearance and includes any article intended for use as a component of cosmetic.

f) Object of N.D.P.S.Act- (2marks)

- To consolidate & amend law relating to Narcotic Drugs
- To make strict provision to prohibit, control & regulate the operations relating to Narcotic Drugs & Psychotropic Substances
- To provide matter connected therewith.

(g) Difference between bonded &non bonded laboratory (1mark for each point, any 2 points)

Sr.no.	Bonded laboratory	Non bonded laboratory
1	It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has not been paid.	It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has been paid.
2	Alcohol on which duty has not been paid shall be used under the excise supervision	Only the alcohol on which duty has already been paid shall be used
3	License required should be obtained from Excise Commissioner	License required should be obtained from the officer as the State Government may authorize on this behalf
4	Preparations are deemed to be manufactured in bond when they are manufactured in premises licensed for this purpose.	Preparations are deemed to be manufactured outside bond when they are manufactured in premises licensed for this purpose.

h) **First register**- (1 mark,)

1) The first register is the register restricted by allowing the entry to only those persons who have requisite scientific & professional knowledge in the profession of pharmacy.

2) The names of such persons is to be registered. As soon as the Pharmacy Act, 1948 has taken effect in the state, the first register of pharmacist is required to be prepared by State Government concerned.

3) After the preparation of first register, State Pharmacy Council is to be constituted & the first register to be handed over to State Pharmacy Council for further maintenance.

Subsequent register- (1 mark)

After the preparation of first register & before ER have taken effect in the State, a person who has attained age of 18 years of age, shall on payment of prescribed fee he entitled to have his name in the register if he resides or carries on the business or profession of pharmacy in the state.

(i)**Magic Remedy**- (2marks)

It includes Talisman, Mantra, Kavacha, & any other charm claiming to possess miraculous powers:

i) For diagnosis, treatment & prevention of any diseases in human being or animals, OR

ii) For affecting or altering the structure or organic function of the body or animal.

(j**) Purpose of Poison Act** (2marks)

- To regulate & control import, possession & sale of poisons.

According to the provision of Poison Act,1919

- Central Govt. has been authorized to regulate the import of poisons in India. &
- State Govt. has been authorized to make rules to regulate possession & sale of poison within their respective areas.

(k) **Sale of split quantities of formulation**- (2marks)

- No dealer shall sell loose quantity of any formulation drawn from a pack of such formulation at a price which exceeds the pro-rate (retail) price of formulation plus 5% thereof, provided such formulations shall not be compounded at the premises of the dealer.

(l) **Lunatic**- (1mark)

Has the meaning assigned to it in section 3 of the Indian Lunacy Act 1912.

Minor- (1mark)

A person who under the provision of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.

Q.2 **Pharmacist in relation to his Trade** (3 marks)

A] Price Structure-

- Prices of drugs & medicinal preparations charged from the customers should be fair & including dispensing & compounding charges without unduly taxing the purchaser.

B] Fair trade practice-

- **A** pharmacist should not make any attempt to capture the business of fellow pharmacist by unhealthy competition i.e. by offering reduced price, gifts, prizes etc.
- Trade mark, labels, symbols or any other signs of other pharmacist should not be copied or imitated.
- Drugs or other ingredients required should always be purchased from reputable sources.

C] Hawking of drugs & other-

- Hawking of drugs & medicines should not be practised & any attempt should not be made to collect the orders from door to door.
- Self servicing method in the pharmacy or drug stores should not be allowed as it would encourage self medication which is undesirable & dangerous

D] Advertisement & display-

- There should not be any display or advertisement on the premises, in the newspaper or elsewhere regarding the abilities & services provided by the pharmacy.
- The pharmacist should not make such advertisements which contains:

(i) Misleading or exaggerated statements

(ii) A guarantee of therapeutic efficiency.

(iii) The word ‘cure’ in reference to an ailments or symptoms of ill-health

b) Recommendations of Drug Enquiry Committee (DEC) (1/2 mark for each point, any 6 points)

The main recommendations are –

1) Formation of Central Pharmacy Councils & State Pharmacy Councils which would look after the education & training of professionals. These councils would maintain the register containing the names & addresses of the registered pharmacists.

2) Formation of Central Legislation to control drugs & pharmacy.

3)Setting up of test laboratories in all states to control the quality of production of drugs & pharmaceuticals.

4)Setting up of control laboratories to control the quality of imported drugs & to test the samples sent by the courts.

5) Setting up of courses for training in pharmacy

6) Prescribing minimum qualification for registration as pharmacist.

7) Appointment of an Advisory Board to advice the Govt. in making rules.

8) Development of the drug industry in India.

9) Control of the crude single drugs as well as the compounded medicine used in indigenous system of treatment.

c**) Classes of drugs prohibited to import under D & C Act-** (1/2 mark for each point, any 6)

No person shall import:

1. Any drug which is not of a standard quality. (For this purpose standard quality means standard specified in second schedule of the Act).

2 .Any misbranded drug .

3. Any adulterated or spurious drug .

4. Any patent or proprietary medicine, the true formula or list of active ingredients with their quantities, is not displayed in the prescribed manner on the label or container thereof.

5. Any drug which by means of any statement, design or device or by other means purports or claims to cure or mitigate any such disease or aliment as specified in schedule J or the Rules.

6. Any drug the import of which is prohibited by rules.

7. Any drug for which license is prescribed for its import, but not imported in accordance with such license.

8. Any drug in contravention to any provisions of the Act & Rules thereunder.

(d) **Loan License** –(1½ marks)

1) A loan license means a license which a Licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee.

2) Loan licenses are issued for the manufacture for sale or distribution of drugs other than those specified in schedulec,c1 & x.

3) Application for the grant or renewal of such license shall be made in Form 24-A & the license shall be issued in Form 25-A.

4) A loan license 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.

Repacking licenses-–(1½ marks)

1) License required for the repacking of drugs other than those specified in schedule C and C1.

2) License for repacking of the drugs can be had on application to the licensing authority just like other manufacturing licenses.

3) Application for the grant or renewal of such license shall be made in Form 24-B & the license shall be issued in Form 25-B.

4) Persons licensed to repack drugs should observe adequate space & equipment for the repacking operations which must be carried out under hygienic conditions & under supervision of Competent Person.

5) The drugs repacked should, in addition to other particulars, bears the no. of license preceded by the words 'Rpg. Lic. No.' on their label.

(e**) Geneva Convention**: (3 marks)

The Geneva Conventions comprise four treaties, and three additional protocols, that establish the standards of international law for the humanitarian treatment of the victims of war.

The singular term *Geneva Convention* denotes the agreements of 1949, negotiated in the aftermath of the Second World War (1939–45), which updated the terms of the first three treaties (1864, 1906, 1929), and added a fourth treaty.

The articles of the Fourth Geneva Convention (1949) extensively defined the basic, wartime rights of prisoners (civil and military); established protections for the wounded; and established protections for the civilians in and around a war zone.

The treaties of 1949 were ratified, in whole or with reservations, by 194 countries. Moreover, the Geneva Convention also defines the rights and protections afforded to non-combatants, yet, because the Geneva Conventions are about people in war, the articles do not address warfare proper — the use of weapons of war — which is the subject of the Hague Conventions (First Hague Conference, 1899; Second Hague Conference 1907), and the bio–chemical warfare Geneva Protocol (Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, 1929).

A resolution was unanimously passed on 15th July 1999 stating that the Fourth Geneva Convention does apply to Israeli settlements in the "occupied territories."

(f) Explanation: (1 mark for each)

i) **Spirit** -means plain un-denatured alcohol of a strength not less than 50.0 over proof and includes absolute alcohol.

ii) **dutiable goods** - means the medicinal and toilet preparations specified in the Schedule as being subject to the duties of excise levied under this Act;

iii) **collecting Government** - means the Central Government or, as the case may be, the State Government which is entitled to collect the duties levied under this Act;

Q.3) Solve any Four of the following

a) Six functions of P.C.I. are as follows: (Each point carries ½ marks)

1) To prescribe the minimum standards of education required for qualification as a pharmacist this can be provided by making the rules as education regulations, which prescribe minimum standers i.e., minimum qualification for admission, duration of the course, details of the syllabus, practical, training and examinations, minimum facilities required for conduct of course.

2)To regulate the minimum education standards (For this purpose council appoints inspector to inspect institution), providing the minimum standard in education in pharmacy and report the facilities available and decides whether the institute should be recognized or not.

3To recognize qualification granted outside territories to which pharmacy act 1948 extends for the purpose of qualifying for registration, under the said act.

4)To compile and maintain a central register for pharmacy containing names of all persons for the time being entered in state register.

5)The Council has to furnish copies of its minutes and those of executive committee, together with the summary of annual activities and accounts to the central Government.

6)Any other function, that will be assigned to the central council to fulfill the objective of pharmacy act 1948.

b) **The classes of advertisements, which are prohibited under Drugs & Magic Remedies (O.A.) Act are:** (Each point carries 1 marks) (3)

I) Advertisement of drugs which may lead to its/their use for the treatment of certain diseases and disorders:
- i) For procurement of miscarriage or prevention of conception in women; or
- ii) For the correction of menstrual disorders; or
- iii) For the maintenance of power of human being.
- iv) For diagnosis, cure, alteration, treatment or prevention of any disease or disorder or condition specified in the schedule or in rules made under the act.

II) Advertisement of magic remedies for treatment of certain diseases or disorders which may claim to be efficacious for any above purposes.

III) Misleading advertisement in relation to drugs, which:
- i) Directly or indirectly gives false impression regarding true character of drugs.
- ii) Makes false claim of drugs.
- iii) Is otherwise false or misleading in any material particularly.
- iv) Ayurvedic remedies to cure liver disorders & memory enhancement.

c) Offences and penalties under Poison Act are:

Offences-(1½ marks)

1. Unlawful possession for sale & sale of poison.
2. Importation without a licence of any poison the importation of which is for the time being restricted by the Central Government.
3. Breach of any condition of a licence for the importation of any poison granted to him is punishable.

Penalties--(1½ marks)

a) With imprisonment upto 3 months or with fine upto Rs.500/- or with both, on a first conviction.
b) With imprisonment upto 6 months or with fine upto Rs.1000/- or with both, on a second or subsequent conviction.

The poison in connection with the offence, together with the vessels, packages or coverings is liable for confiscation.

d) **Define**

i) Retention price (2 marks)

Retention price in relation to bulk drug is defined as the price fixed under paras. 4 &71 (which shall be the maximum retention price) for individual manufacturers, or importers, or distributors of such bulk drugs.

ii) Pooled price (1 mark)

Pooled price in relation to a bulk drug is defined as the price fixed under para 7.

e) Handling of Prescription according to Code of Ethics :- (Each point carries ½ marks)

1) When a prescription is presented for dispensing it should be received by the pharmacist without any comments or discussion over it, regarding the merits and demerits of its therapeutics efficiency, should not show any physiognomic facial expression.

2) He should answer any question on the prescription to the customers with caution and care. He should not disclose any secrecy of the prescription to the customers.

3) He should not add, omit or substitute any content of prescription without the consent of the prescription.

4) In case of any error or doubt in a prescription it should be referred back to the prescriber.

5) In such case, the customer should not feel doubt about the efficacy of the prescription or it should not affect the reputation of the prescriber.

6) At the time of dispensing the prescription, he should guide and advice the patient about the use of medicines as per instruction of prescriber.

f) Different conditions, under which pregnancy can be terminated under act by R.M.P. are as follows:

1) The Registered Medical Practitioner may terminate a pregnancy when it is not more than 12 weeks old and the Medical Practitioner is of the opinion formed in good faith, that- (1 mark)
   a) Its continuance would result into serious injury to the physical or mental health of the pregnant women, or,
   b) The child to be born would be seriously handicapped due to physical & mental abnormalities.
2) The Registered Medical Practitioner may terminate a pregnancy when it is not more than 12 weeks but not more than 20 weeks, if not less than 2 registered medical practitioners are of the opinion mentioned in one above where any pregnancy is alleged by the pregnant women to have been caused by rape or as a result of failure of any contraceptive device used by any married women or her husband for the purpose of family planning, it may presumed to constitute a grave injury to the mental health of the pregnant women. (1 mark)

   To determine whether, the continuance of a pregnancy would result into grave injury to the physical & mental health, the pregnant women's actual or reasonable foreseeable environment may be taken into consideration.
3) The Registered Medical Practitioner may terminate a pregnancy of a woman of 18 years of age or more with her written consent. (½ marks)
4) The Registered Medical Practitioner may terminate a pregnancy of a woman who is less than 18 years of age or who attained the age of 18 years & is lunatic, with written consent of her guardian. (½ marks)

Q.4) Solve any FOUR of the following:

a) "General licences" and "Restricted licences" under D & C Act

For retail sale two types of licences are issued

i) General licences
ii) Restricted licences

i)General licences (1 mark)

General licences are granted to 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.

Licenses for retail sale of drugs other than those specified in Schedule C,C1 and X are issued in form 21 and for Schedule X drugs in Form 20F.

5) Restricted licences (2marks)

The lienses for the restricted sale of drugs other than those specified in Schedule C,C1 but not in Schedule X are issued in form 20A and 21A respectively.

Restricted licences can be given to –

i) Dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.

ii) Itinerant vendors in exceptional cases, for bonafide travelling agents of firms dealing in drugs, or
iii) To a vendor who purchases drugs from a dealer for distribution in sparsely populated areas where other channels of distribution of drugs are not available.
iv) Restricted licences may also be issued to a travelling agent of a firm for the special purpose of distribution to the medical practitioners or dealers, for supply of biological and other special products specified in Schedule C.
v) Travelling agents of licensed manufacturers, agents of such manufacturers and importers of drugs need not take licenses for the free distribution of samples of medicines to any member of medical profession, hospitals, dispensaries and research institutions.

b) The following are the general requirements of labeling drugs:

(Each point carries ½ marks)

i) Proper name of the drug along with trade name, if any. In books of standards or in a schedule to the rules or in the international standard prescribed by agencies like W.H.O The proper name should not be less conspicuous that the trade name.
ii) Statement of net contents of weight, volume or number of units as the case may be.
iii) Quantities of active ingredients expressed in terms of amount per single dose. For oral liquids the quantities may be expressed per 5ml or multiples thereof and if the dose be less than 5 ml. The quantity per milliliter. In parenteral per milliliter or as percentage of volume or for single dose containers quantities per dose. In solid drugs for parenteral use the quantities may be given as units or weight per gram or milligram. In case of unit dosage forms like tablets, capsules etc., and the quantities may be given per unit and for other preparation in terms of percentage by weight of volume or as unit age per gram or per milliliter as the case may be.
iv) Name and address of the manufacturer.
v) Distinctive batch number by reference to which details of manufacture can be looked up. The number should be preceded by words like batch No. , B. No. , Lot. No. , Lot. Etc.
vi) Manufacturing licence number preceded by word like mfg Lic. No. , M. L . No. , Manufacturing licence No. , etc.
vii) Date of manufacture and in case of drugs in Schedules P and C the expiry date.

c) Procedure to be followed by the drug inspector for taking samples of "insulin injection" from selling premises: (3 marks**)**

1. Intimate the purpose to a person from whom, he takes sample, in writing in a prescribed Form (form-17)
2. Tender fair price of the sample and obtain acknowledgement thereof . if price is refused, by such person, he has to tender receipt thereof in prescribed form (form-16-A)
3. Divide the sample in the presence of such person in four parts unless he willfully absents himself and effectively seals and mark the portions so sealed.
   Insulin injection is packed in small volume container it gets damaged or deteriorates on exposure, so three or four containers to be taken and sealed and marked.
4. a) Restore one portion or container with a person from whom sample is taken.
   b) Send one portion/container to the Government analyst for test or analysis.
   c) Reserve one portion/container for production before the court if proceedings are instituted in case of such examples.
   b) Send remaining portion to a warrantor, if any, (whose name address and other particulars have been disclosed).

d) Define: (Each def. carries 1 mark)

i).AYURVEDIC DRUGS

It includes all medicines intended for , diagnosis , treatment , mitigation or prevention of disease or disorder in human being or animals and manufactured in accordance with the formulae , described in authorative books of Ayurveda system of medicine , specified in first (I st) Schedule .

ii) COSMETICS

It means any article intended to be rubbed , poured , sprinkled or sprayed on or introduced into or applied to any part of human body for cleansing , beautifying , promoting attractiveness of altering the appearance and include any article intended for use as a component of cosmetic.

iii. MANUFACTURE

It means - any process or a part of process for making, altering, ornamenting, finishing, packing , labeling, breaking up or otherwise filtering or adopting any drug or cosmetic for sale or distribution , but does not including any compounding or dispensing of any drug or packing of drug or any cosmetic in ordinary course of retail business.

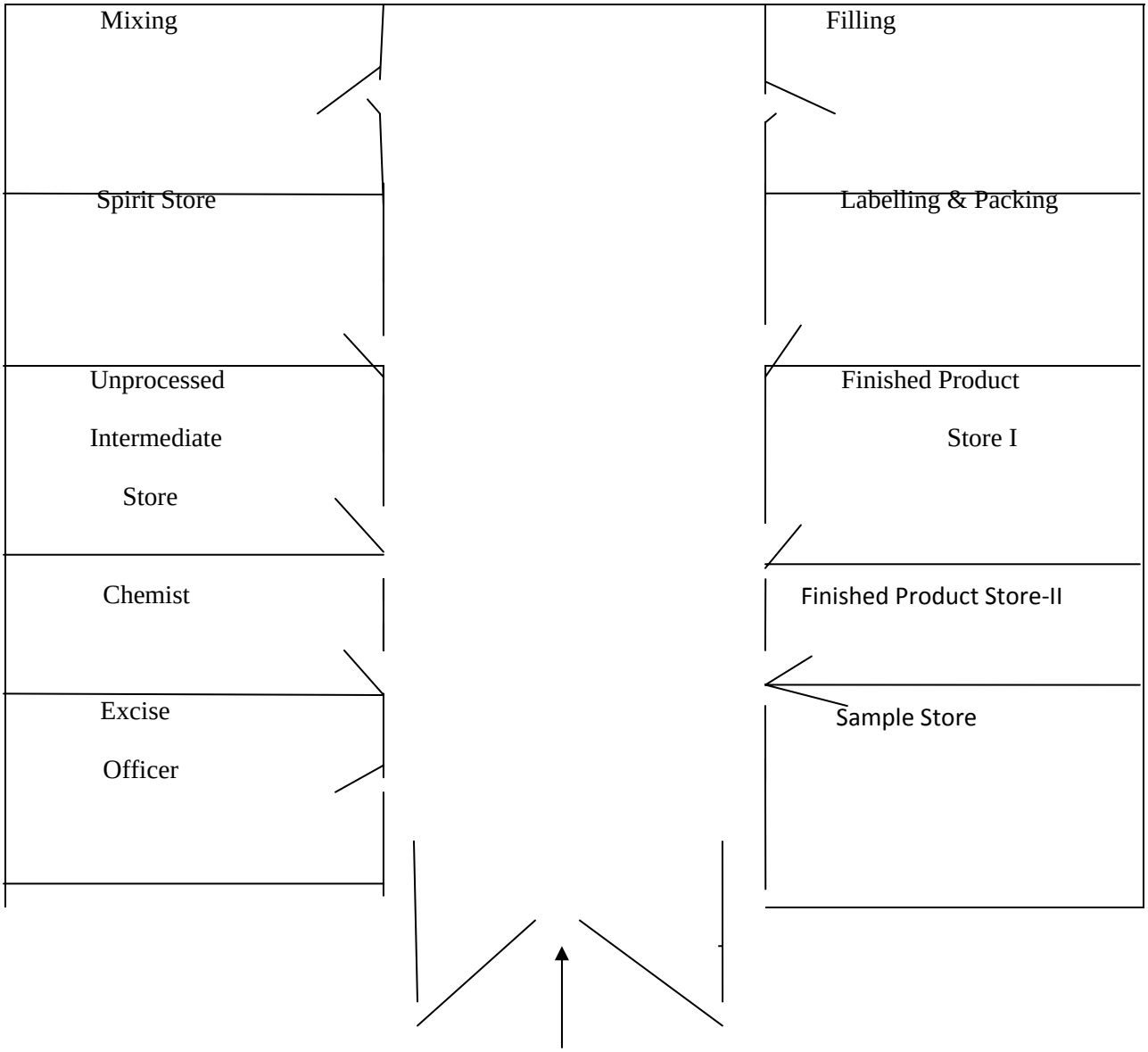
e) Layout plan of bonded laboratory: (3 marks)

I. The bonded laboratory should have:

1. The spirit store room.
2. One large room for manufacturing medicinal preparations.
3. One or more rooms for storing finished medicinal products.
4. Separate manufacturing room & finished product & storing room for toilet preparations.
5. Accomodation near the entrance for the excise incharge & necessary furniture.
6. The spirit store room.
7. One large room for manufacturing medicinal preparations.
8. One or more rooms for storing finished medicinal products.
9. Separate manufacturing room & finished product & storing room for toilet preparations.
10. Accomodation near the entrance for the excise incharge & necessary furniture.

II. There shall only one entrance in lab & one door to each of its compartments.
III. Every window shall be provided with 19mm thick malleable iron rod set,10.2mm apart, shall be covered from outside with strong wire netting of mesh not exceeding 25mm.
IV. Every room should bear a board indicating a name of room & serial number.
V. All pipes, sinks, wash-basins inside the lab shall discharge into the general drainage directly.
VI. The gas & electric connections shall be cut off at the end of work.
VII. All vessels intended to hold alcohol & other liquid preparations should bear distinctive serial no. with their full capacity marked individually.
VIII. The alcohol storage vessel shall bear excise ticket lock.
IX. The lab can be opened only in presence of excise officers incharge, at the end of days work, it shall be closed with excise ticket-lock.

BONDED LABORATORY (GENERAL DESCRIPTION) LAYOUT



f) Rules & regulations for storing of alcoholic preparations in bonded warehouse are:

(Each point carries ½ marks, any 6 points)

1) The persons who intend to establish a warehouse should apply in prescribed form along with prescribed fees to Excise commissioner of State & obtain a license for the purpose .

2) The Excise commissioner may require the liensee to furnish a bond in prescribed form with surety or security**,** binding him to pay duty on the goods deposited or for the removal of such goods to another warehouse

3) Goods may be kept in a warehouse for a maximum period of 3 year from the date of their deposit or for such extended periods , as may have permitted by the Excise Commissioner .
4) On the expiry of three years or the extended period , if any , the goods must be removed from the warehouse and duty paid on them.
5) While in the warehouse, the goods should remain in the condition in which they were received .
6) The officer-in-charge may, however , sanction them to be sorted , separated , packed or repacked with a view to facilitate their scale or disposal .
7) If goods are lost or damaged in the warehouse the matter should be immediately brought to the notice of the officer-in-charge . If ,on receiving the report of the officer-in-charge , the Excise Commissioner is satisfied that the loss or damage was due to circumstances beyond the control of the licensee , he may remit the duty chargeable on the same .
8) No non-deductible goods should be deposited in a licensed warehouse . The Excise Commissioner may direct as to how the warehouse should be locked & secured , but the licensee shall be responsible for the safety of the goods in the warehouse at all times .

Q.5. SOLVE ANY FOUR OF THE FOLLOWING:

(a) EDUCATION REGULATIONS: (1 mark for definition and 2 marks for all points)

Subject to the provision of section 10 of the Pharmacy Act, 1948, Central Council after approval of the Central Government may make regulations prescribing the minimum standard of education required for qualification as pharmacist called Education Regulations and prescribe:

1. Minimum qualification for admission to the course.

2. Nature and period of course of study.

3. Nature and period of practical training to be undertaken after completion of regular course (Not less than 500 hours covered in a minimum of 3 months in an institution, hospital, pharmacy or dispensary recognized by Central Council).

4. Subjects of examination and standards attained therein.

5. Equipment and facilities to be provided by institutions for students undergoing approved course of study.

6. Conditions to be fulfilled by institutions giving practical training.

7. Conditions to be fulfilled by authorities holding approved examinations.

(b) PROVISIONS FOR SALE OF POISONS: (1/2 mark for each point)

The State Government has power to make rules in this connection which may provide for –

1. The grant of licences for the possession for sale, wholesale or retail of any specified poison and fixing of fees to be charged for licences.

2. The classes of persons to whom the licences for the possession for sale and sale of poisons are to be granted.

3. The maximum quantity of any poison that may be sold to a person.

4. Maintenance of registers for the sale of poisons and inspection of the same.

5. Safe custody of poisons and labeling of vessels, coverings or packages in which such poison is sold or stored for sale.

6. Inspection and examination of any such poison possessed for sale by any vendor.

(c) FIXING PRICES OF BULK DRUGS: (3 marks)

Under the provisions of DPCO 1995 to achieve the objectives of this order, Government has power to fix maximum sale price and also to revise the prices of bulk drugs after obtaining necessary information from a manufacturer or importer.

While fixing sale prices of such bulk drugs, the govt. shall take into consideration

i. a post-tax return of 14% on net worth or

ii. a return of 22% on capital employed or

iii. for a new plant, a return of 12% based on long term marginal costing

iv. in cases where the production is from basic stage, a post-tax return of 18% on net worth or 26% on capital employed.

depending upon option for rates of return exercised by manufacturer.

No person shall sell a bulk drug at a price exceeding the maximum sale price fixed as per provisions of this order plus local taxes if applicable.

(d) EXPERIENCE AND TRAINING OF RMP FOR TERMINATION OF PREGNANCY: (1 mark for each point)

MTP Rules 1975 prescribe experience or training in gynaecology and obstetrics for RMP to terminate a pregnancy.

1) A medical practitioner registered in a state medical register immediately before commencement of the Act should have not less than 3 years experience in practice of gynaecology and obstetrics.

2) A medical practitioner registered in a state medical register on or after the date of commencement can terminate pregnancy.

i). If he has completed 6 months of house surgency in gynaecology and obstetrics or

ii). If he has experience at any hospital for a period of not less than 1 year in the practice of gynaecology and obstetrics or

iii). If has assisted RMP in the performance of 25 cases of medical termination of pregnancy in a hospital established or maintained, or a training institute approved by the govt. for this purpose.

3) In case of RMP who holds a [post-graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of such degree or diploma is considered.

(e) EXPLANATION:

1). **Pharmacist is a liason between medical profession and public** –(½ marks for each point)

i)The pharmacist is constantly in touch with modern development in pharmacy and allied fields.

ii)He is an expert in the field of pharmacy so that he may advise the physicians on pharmaceutical matters.

iii)By enlarging his store of knowledge he may be able to educate the public to maintain their health.

2**). Pharmacist is a law abiding citizen** – (½ marks for each point)

i)A pharmacist should observe the law and ethical principles to maintain the standard of the profession.

ii)He should have a fair knowledge of laws of the state and nation pertaining to food, drug, pharmacy education, health, etc.

iii)A pharmacist should not perform such acts which will bring discredit to his profession or to himself in the society.

(f) DEFINE: (1 ½ marks for each definition)

Drug Inspector – Means

i. In relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by Central or State Govt under Section 33-G;

ii. In relation to any other drugs or cosmetics, an Inspector appointed by Central or State Govt. under Section 21.

Govt. analyst – Means

i. In relation to Ayurvedic, Siddha or Unani drugs, a person appointed under section 33-F;

ii. In relation to any other drugs or cosmetics, a person appointed under section 20 of Drugs and Cosmetics Act.

Q.6 SOLVE ANY FOUR OF THE FOLLOWING:

(a) SCOPE OF PHARMACEUTICAL LEGISLATION: (2marks, any 4 points)

i)It is related with legal system which regulate the conduct of pharmacy business & practice of profession of pharmacy.

ii)A thorough understanding of all laws pertaining to pharmacy is essential & all legal aspects must be satisfied by those who wish to practice the pharmacy business.

iii)I t helps the pharmacist to understand their legal & ethical responsibilities & their by avoid the danger of unnecessary legal proceedings.

iv)The patient should gets the drugs of good quality which are tested & evaluated for safety purpose.

v)It also covers the legal aspect relating to manufacture of drugs in Pharmaceutical industries, their storage, sale, distribution.

vi)The Pharmaceutical Legislation safeguards the health of the people by making right medication by controlling pharmacy business & profession.

OBJECTIVE OF PHARMACEUTICAL LEGISLATION(2marks, any 4 points)

i)To promote health care by regulating the manufacture, supply & distribution of good quality drugs.

ii) To make these drugs available to the public at reasonable prices & through qualified person

iii)To safeguard the people from misleading & false advertisements relating to drugs & remedies

iv)To regulate the profession of pharmacy.

v)To promote the Indigenous research technology.

(b) CONCEPT OF PHARMACY AS A PART OF HEALTH CARE TEAM: (4 marks)

i)All the pharmacists working in different fields of profession are directly or indirectly related to nation’s health.

ii) Community pharmacist and hospital pharmacists are health professionals for the safe and effective use of drugs.

iii) Pharmacy occupies an important position in the health care system. So the pharmacist should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product.

iv)Pharmacist is legally held responsible for the quality of product which is manufactures and distributed. They supply medicines against prescriptions. They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes.

v)They provide link between Physician & Patient

vi)They are able to advice patients with minor illness

vii)The profession of Pharmacy presently consist of

- Industrial pharmacist
- Hospital pharmacist
- Academic pharmacist
- Community pharmacist

viii)Pharmacist has to play an important role in areas such as:

1. Prescription adherence.

2. Storage and distribution of drugs.

3. Drug choice.

4. Drug monitoring.

5. Information and education.

6. Clinical pharmacokinetics.

7. Research and development and many other health activities.

(c) CLASSES OF COSMETICS PROHIBITED: (1/2 mark for each point, any 8 points)

1. Misbranded or spurious cosmetics and cosmetics not of standard quality.

2. Cosmetics containing any ingredient which makes them unsafe or harmful for use under directions indicated or recommended.

3. Cosmetics imported or manufactured on contravention of any provisions of the Act and the Rules –

4. Cosmetics containing hexachlorophene.

5. Cosmetics containing coal tar colour other than the one prescribed.

6.. Cosmetics containing prescribed colours which contain more than 2 ppm of arsenic or 20 ppm of lead or 100 ppm of heavy metals other than lead.

7. Cosmetics intended for use on eye-brow or eyelash or around the eye containing any coal tar dye colour, coal tar base or coal tar dye intermediate.

8. Cosmetics containing mercury compounds.

9. Cosmetics coloured with arsenic or lead compounds.

(d) PROVISIONS FOR EXCISE DUTY ON AYURVEDIC ALCOHOLIC PREPARATIONS: (4 marks)

Ayurvedic preparations containing alcohol may be of 2 types –

1. Those containing self-generated alcohol e.g. asavas

2. Those prepared by distillation or to which alcohol is added at any stage of manufacture.

Duty shall not be levied on Ayurvedic preparations containing self-generated alcohol in which alcoholic content is less than 2%. If it is more that 2% and if it is capable of being consumed as ordinary alcoholic beverages, the duty shall be paid, otherwise not.

Registered Ayurvedic practitioners are allowed to manufacture and dispense (except by distillation or by addition on alcohol during the process) such preparations free of duty, provided:

i. They take a licence.

ii. Use such preparations only for patients of practitioners and not for sale to the general public.

iii. They should allow Excise Officer to draw samples of such preparations to ensure that the preparations contain only self-generated alcohol; and

iv. They should maintain accounts of preparations manufactured or dispensed to patients together with the names and addresses of patients.

(e) REMOVAL OF NAMES FROM THE REGISTER: (4 marks)

The Executive Committee after giving an opportunity to the person concerned to explain his conduct and on sufficient inquiry if satisfied orders to remove the name of registered pharmacist on following conditions:

1. If his name has been entered in the register by error or on account of misrepresentation or suppression of material fact or

2. If he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect which in the opinion of Executive Committee renders him unfit to be kept in the register or

3. That a person employed by him to work under him, in connection with any business of pharmacy has been convicted of an offence or held guilty of any such infamous conduct, if such person is a registered pharmacist, he is liable to remove his name from register.

(f) DEFINE: (1 mark for each definition)

i. **Coca leaf** – It includes

1. The leaf of coca (Erythroxylon) plant (excluding the leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed)

2. Any mixture thereof with or without any neutral material and does not include any preparations containing less than 0.1% of cocaine.

ii. **Opium** – It means the coagulated juice of the opium poppy and its mixture with or without neutral material (excluding the preparations containing less than 0.2% of morphine).

iii. **Cannabis** – It includes the following:

1. Charas which is a resin in crude or purified form obtained from cannabis plant which includes concentrated preparations and a resin known as hashish oil or liquid hashish.

2. Ganja which comprises of flowering or fruiting tops of cannabis plant (excluding seeds and leaves not accompanied by the tops).

3. Any mixture with or without any neutral material of ganja or charas or any drink prepared from them.

iv. **Psychotropic substances** – It means any substance natural or synthetic or any salt or preparation of such substance or material which is included in the list of psychotropic substances specified in the schedule.