SUMMER-15 EXAMINATION

Subject Code: **0814** **Model Answer** Page No: 1/28

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.

2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.

3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.

4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any

equivalent figure drawn.

5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.

6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.

7) For programming language papers, credit may be given to any other program based on equivalent concept.

Q. No. 1. Attempt any EIGHT of the following **16 marks**

(a) Define "misbranded drug" under D & C Act, 1940. (2 marks)

A drug shall be deemed to be misbranded if-

i) 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

ii) It is not labelled in the prescribed manner, or

iii) 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.

(b) Give the object of N. D. P. S. Act, 1985. (2 Marks)

The main object of this act is

i) To consolidate & amend the law relating to narcotic drugs,

ii) To make stringent provision for the control & regulation of operations relating to narcotic drugs & psychotropic substance &

iii) To provide matters connected therewith.

(c) Give the objectives of Poisons Act, 1919. (2 Marks)

The main object of passing this act was to regulate & control the import, possession and sale of poisons.

(d) Define "Registered Pharmacist" as per Pharmacy Act, 1948. (2 Marks)

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.

(e) Give offences and penalties (any one) under the Drug and Magic Remedies (O. A.) Act, 1954. (Any one offence& penalty 2 Marks)

Offences & Penalties under Drugs & Magic Remedies (O.A.) Act, 1954

1) Contravention of any of the provision of this Act or Rules thereunder:
   -Punishable with imprisonment six month or with fine or with both on first conviction.
   -Punishable with imprisonment one year or with fine or with both on subsequent conviction.
2) In case of contravention of the provisions of the Act by a company, every person who at the time of the commission of the offence, was in-charge of & was responsible for the conduct of company business shall be deemed to be guilty & liable for the punishment.
   However, such person is not liable for the punishment if he proves that the offence was committed without his knowledge or he has taken all the precautions to prevent that the commission of such offence.

(f) Define "Lunatic and Minor" under Medical Termination of Pregnancy Act, 1971. (1 Mark each)

Lunatic- Has the meaning assigned to it in Section 3 of the Indian Lunacy Act, 1912.

Minor- Means a person who, under the provisions of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.

(g) Give four examples of Schedule "C" drugs. (Each example ½ Marks, any 4)

- Sera,
- Solution of serum proteins intended for injection
- Vaccines for parenteral injections
- Toxins,
- Antigens,
- Antitoxins,
- Neo-arsphenamine & analogous substances used for the specific treatment of infective diseases
- Insulin,

- Pituitary extract
- Adrenaline & solutions of Salts of Adrenaline
- Antibiotics & preparations thereof in form to be administered parenterally
- Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product & which-
  - Requires to be stored in a refrigerator; or
  - Does not requires to be stored in a refrigerator
- Sterilized surgical Ligature & sterilized surgical suture
- Bacteriophages
- Ophthalmic Preparations,
- Sterile Disposable Devices for single use only.

(h) Define "Bulk Drug" under DPCO, 1995. (2 Marks)

Bulk Drug : It means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereoisomers and derivatives conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation

(i) Give the ex-officio members of Pharmacy Council of India. (2 Marks)

Following are the ex- officio members of Pharmacy Council of India-

- Director General of Health Services
- Drugs Controller of India
- Director of the Central Drugs Laboratory

(j) Give two points of difference between bonded and non-bonded laboratory. (Each point 1 mark, any two 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	Excise duty payable on removal of goods from bonded laboratory.	Excise duty payable at the time of spirit purchase.
3	Bonded laboratory to function under Excise staff.	No excise staff is required.
4	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.
5	Suitable for large scale manufacture.	Suitable for small scale manufacture.

(k) State the functions of Central Drug Laboratory (any two.) (Each point 1 mark, any 2)

1) To analyse or test the samples of drugs as may be sent to it by
   i) Custom collector or any other authorized officers or
   ii) courts
2) To carry out such other duties as may be entrusted to it by Central or by State Govt. after consultation with the Drugs Technical Advisory Board.

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

- Sera, Solution of serum proteins intended for injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature and sterilized surgical suture & Bacteriophages.
- The functions regarding Oral Polio Vaccine are exercised by the Deputy Director & Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute Kasauli.

4) In case of the following drugs or classes of drugs shall be carried out at the Indian Veterinary Research Institute, Izatnagar or Mukteshwar. Such functions are exercised by the Director of either of the said institutes:- Anti-sera, Vaccines, Toxoids, Diagnostic Antigens for veterinary use.

5) In case of condoms the functions of CDL are carried out at the Central Drugs Testing Laboratory, Chennai, and such functions are exercised by the Director of the said Laboratory.

6) In case of VDRL Antigen the functions of CDL are carried out at Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions are exercised by Director of Serologist and Chemical Examiner of the said Laboratory.

7) In respect of Intrauterine Devices and Falope Rings, the functions of laboratory shall be carried out at the Central Drug Testing Laboratory, Thane, Maharashtra and such functions shall be exercised by the Director of the said Laboratory.

8) In respect of human blood and human blood products including components, to test for freedom of HIV antibodies, shall be carried out by the following Institutes, Hospitals and such functions are exercised by the head of the respective Institutes-

i) National Institutes of Communicable Disease, Department of Microbiology, Delhi.

ii) National Institute of Virology, Pune

iii) Centre of Advanced Research in Virology, Christian Medical College, Vellore.

9) In respect of Homoeopathic medicines the functions of CDL carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said laboratory.

10) In respect of Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus the function of CDL carried out at the National Institute of Biologicals, NOIDA and such functions are exercised by the Director of the said laboratory.

(l) Give two points difference between law and ethics. (Each point 1 mark, any 2)

Sr. No	Law	Ethics
1	Rules of human conduct binding on all persons in a state or nation.	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 cannot force him to help his neighbour in hours of need.	Helping the neighbour 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 are 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 previleges.

Q. No . 2. Solve any FOUR of the following: 12 Marks

(a) What are "Education Regulation"? And explain what they state.

Education Regulation (1 Mark)

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

The Education Regulations may prescribe – (2 Marks)

i) Minimum qualification for admission to the course.

ii) Nature & period of course of study.

iii) Nature and period of practical training to be undertaken after the completion of regular course. (Not less than 500 Hrs. covered in a minimum of 3 months in an Institution, Hospital, Pharmacy or dispensary recognized by Central Govt.)

iv) The subjects of examination and the standards to be attained.

v) The equipment and facilities to be provided by the institutions for students.

vi) Conditions to be fulfilled by institutions giving practical training.

vii) Conditions to be fulfilled by authorities holding approved examinations.

Central Council before submitting the ER or any amendment thereof, as the case may be to the Central Government for approval, sends copies of draft of ER to all State Governments & takes into consideration the comments of any State Government received within three months. Then ER is published in Official Gazette by Central Government.

(b) Give Qualification of Drug Inspectors prescribed under prescribed under D & C Act, 1940 and Rules, 1945. (3 Marks)

A person who is appointed an Inspector should possess the following qualifications

1) Graduate in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized University.

Provided that for the purpose of inspection of manufacture of substances specified in Schedule C, a person appointed as a Drug Inspector should have -

i) Not less than 18 months experience in the manufacture of atleast one of the substances specified in Schedule C, or

ii) Not less than 18 months experience in testing of atleast one of the substances in Schedule C in a approved Laboratory, or

iii) Not less than three years experience in the inspection of firms manufacturing any of the substances specified in Schedule C during the course of their services as Drugs Inspector.

Provided further that the first 4 years from the date on which Chapter IV of the Act takes effect in the States, person whose qualification, training & experience are considered adequate may be appointed as Inspector & their appointments continued even after 4 years, if the State Govt. is satisfied.

(c) State in brief classes of prohibited advertisements under Drug and Magic Remedies Act, 1954 (any three). (1 mark each, any 3)

Following are the classes of prohibited advertisement-

1) 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 in women; or

iii) For the maintenance or improvement of the power of human beings for sexual pleasure.

Or iv) For diagnosis, cure, alleviation, treatment or prevention of any disease or disorder or condition specified in the schedule or in rules made under the Act.

2) Advertisement of Magic Remedies for treatment of certain diseases or disorders

No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in I as above.

3) Misleading advertisements in relation to drugs, which -

i)Directly or indirectly gives false impression regarding true character of drug or drugs; or

ii)Make any false claims for such drug or drugs

iii) Is otherwise false or misleading in any material are prohibited.

iv) Ayurvedic remedies to cure liver disorders & memory enhancement.

4) Prohibition of import into, & export from India of certain advertisements-

No person shall import into, or export from, the territories to which this Act extends any document containing an advertisement of the nature referred to in section3 or section 4, or section 5, & any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under section 19 of the Sea Customs Act,1878

(d) Write any three recommendations of DEC. (1 mark for each point)

Following are some important recommendations of DEC-

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) Creation of Drug Control Machinery (Departments) at the Centre with the branches in all the states.
3) Establishment of well equipped Central Drug Laboratory (CDL) with competent staff and experts for an efficient and speedy working of Drug Control Department. It was also suggested that the small laboratories would work under the guidance of Central Drug Laboratory.

(e) Write the functions of Pharmacy Council of India. (Each point ½ Mark)

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 qualification for admission, duration of the course, details of the syllabus, practical training and examination, minimum facilities required for conduct of course, examination & practical training)

2) To regulate the minimum educational standard. (For this purpose, Council appoints Inspector to inspect institutions, providing the minimum standards in education in pharmacy and report the facilities available and decides whether the institute should be recognized or not.
3) To recognize qualifications 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 pharmacist 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 may be assigned to the Central Council in the furtherance of the objectives of the Pharmacy Act, 1948.

(f) Define "adulterated drug" under D & C Act, 1940. (Each point ½ Mark)

A drug shall deemed to adulterated-

i) If it consists, in whole or in part, of any filthy, putrid or decomposed substance, or,
ii) If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or it may have been rendered injurious to health, or,
iii) If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
iv) If it bears or contains, a colour other than prescribed which may be used for the purpose of colouring only; or
v) If it contains any harmful or toxic substance which may render it injurious to health or
vi) If any substance mixed with it so as to render its quality or strength.

Q 3. Solve any FOUR of the following: 12 marks

(a) Write the building arrangements of non-bonded laboratory. (any 6 points, 3marks)

Building arrangements.- Arrangement of the building shall be as under **:**

(i) The portion of the non-bonded laboratory should be separated from the other portion used for other business.

(ii) There should be separate 'spirit store', 'laboratory' & 'finished store' & these should have the windows fitted with malleable iron bars of specific dimensions & the windows should be covered on the inside with strong wire netting of mesh not exceeding 25 mm.

(iii) There shall be only one entrance to the non-bonded manufactory and one door each to the 'spirit store', 'laboratory' and 'finished store'.

(iv) All pipes from sinks and wash-basins inside the should be connected to the general drainage system of the premises.

(v) All electric and gas connections with the licensed premises shall be so fixed as to admit of the supply of electricity or gas being cut off and the regulators or switches being securely locked out at the end of day`s work.

(vi) There shall be separate "spirit store" for the rectified spirit purchased at the duty of Rs.1.10 paise, Rs.3.85 paise and Rs.15.50 paise per London Proof Litre.

(vii) There shall be separate finished stores for medicinal and toilet preparation falling under each item of the Schedule to the Act.

(viii) All alterations in arrangement of building and plants shall be made only with the previous sanction of the Excise Commissioner.

(xi) The State Government may relax all or any of the provisions of Clause. (i) to (viii) in the case of small manufacturers whose annual consumption of alcohol does not exceed 500 liters and also in the case of those who prepare medicinal preparation for dispensing to their patients only and not for sale.

(b) Write the procedure for approval of institution running diploma/degree courses in Pharmacy. (3 marks)

1) **Applications by Institutions / Authority to the Central Council**: An institution or authority, which conducts course of study or holds an examination of the pharmacist, has to apply to the Central Council (PCI) for approval of the course or examination.

2) Inspection: The Central Council, after receiving such applications, depute its inspectors to visit the institution and ascertain whether the institution has the prescribed facilities for imparting training or holding examination in accordance with ER or not. The inspector may also attend any examination to judge its standards without interfering with its conduct. The Inspectors then report to the council on the facilities available at the institution and on conduct and standard of the examination held.

3) Approval: On report of the inspector if council is satisfied, it may accord approval to it and the said course and examination shall be deemed to be approved for qualifying for registration as a pharmacist under act.

4) Declaration: Declaration of approval made by resolution is passed at a meeting of the Central Council and published in official gazette

(c) Write the offences and penalties under Pharmacy Act, 1948. (any 3 points, 3marks)

1) Falsely claiming to be Registered Pharmacist: Any person whose name is not entered in the register falsely claims to be a registered pharmacist or uses in connection with his name any words or letters to suggest that his name is so entered in the register is punishable with fine upto five hundred rupees on first conviction, and with imprisonment upto six months or with fine upto thousand rupees or both on any subsequent conviction.

The use of description such as ‘Pharmacist’, ‘Chemist’, ‘Druggist’, ‘Pharmaceutist’, ‘Dispenser’, ‘Dispensing Chemist’ or any combination of such words by a person indicates that his name is entered in the register of a state.

2) Dispensing by unregistered persons: The persons other than registered pharmacist dispensing any medicine for patients is liable for punishment with imprisonment upto six months or with fine upto one thousand rupees or with both.

3) Failure to surrender certificate of registration: Is also punishable with fine upto fifty rupees.

4) Obstructing State Pharmacy Council Inspectors :-

Penalties :- Shall be deemed guilty of an offence & may be punished with imprisonment upto six month or fine upto 1000 Rs or both

(d) Write the formula for calculation of retail price of drug formulation and explain the term involved in the formula.(formula 1 mark, explanation of terms 2 marks)

Calculation of retail price of formulation:

By applying the following formula, the retail price of the formulation is calculated by the Government.

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

Where **R.P.:-** Means retail price.

M.C.:- means material cost which includes the cost of drugs and other pharmaceutical aids with overages , if any, plus process loss thereon in accordance with the norms specified from time to time by notification in the official Gazette.

C.C.:- means conversion cost worked out in accordance with such norms as may be specified by the Government from time to time by notification in the official Gazette.

P.M.:- means the cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the Government from time to time.

P.C.:- means packing charges worked out in accordance with such norms as may be specified by Government every year by notification in the Official Gazette.

MAPE :- Maximum allowable post manufacturing expenses.

In means all the cost incurred by the manufacturer from the stage of ex-factory cost of

retailing. It also includes trade margin and margin of manufacturer. MAPE shall not exceed 100% for indigenously scheduled formulations.

E.D.:- means excise duty.

(e) Under which conditions the name of registered pharmacist is removed from the register? (3 marks)

The executive committee after giving opportunity to a person 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 due to error, misrepresentation or suppression of material fact.

(2) If he is convicted of an offence in any professional respect, which in the opinion of Executive Committee considered him unfit as a Registered Pharmacist.

(3) If person employed to work under him in connection with any business of pharmacy has been convicted of an offence or held guilty of an infamous conduct.

The removal of names from the register may either be permanent or only for a specified period of time. A person, whose name has been removed from the register is required to surrender his certificate of registration to registrar of the State Pharmacy Council and shall be published in official gazette.

(f) Define:(each definition 1 mark)

Chemist and Druggist:

Licensed premises for the sale of drugs which require the services of a "Qualified Person" but where the drugs are not compounded against the prescriptions.

Drug Store:

Licensed premises for the sale of drugs, which do not require the services of a qualified person.

Pharmacy:

Licensed premises for the sale of drugs which require the services of a "Qualified Person" and where the drugs are compounded against the prescriptions.

Q 4.Solve any FOUR of the following: 12 marks

(a) Give the constitution of State Pharmacy Council as per Pharmacy Act,1948. (all 6 points, 3 marks)

Constitution of State Pharmacy Council:

1) Six members, elected amongst themselves by Registered Pharmacists of state.
2) Five members nominated by the State Government of whom at least three shall be possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or be registered pharmacists.
3) One member elected by the members of Medical Council of the State amongst themselves.

The following are the ex-officio members:

4) Chief administrative medical officer of the state.
5) The officer incharge of the drug control organization in the State; appointed under D.&C. Act,1940.
6) Government Analyst appointed under Drugs and Cosmetics Act, 1940. If there are more than one such Analyst, one may be nominated by the State government.

(b) Under what conditions pregnancies can be terminated by RMP under MTP Act, 1971. (6 conditions, 3marks)

Conditions:

1) A pregnancy may be terminated if it is not more than 12 weeks old & a medical practitioner is of the opinion that continuation of such pregnancy-

i) may involve a serious risk to the life of pregnant woman, & would result into serious injury to the physical or mental health of the pregnant woman,

ii) the child to be born would be seriously handicapped due to physical or mental abnormalities.

2) A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old & 2 RMPs are of the same opinion as above.

3) A pregnancy of any duration may be terminated by RMP when is of the opinion that such termination is immediately necessary to save the life of pregnant women.

4) In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian.

5) The pregnancy caused due to rape or due to failure of contraceptive device used by any married woman or her husband for the purpose of family planning.

6) No pregnancy shall be terminated by a RMP without the consent of the pregnant women except when the pregnant woman is less than 18 yrs. of age and the pregnant woman is lunatic.

(c) Give different instructions and warning which must appear on label of the container or carton of ophthalmic solution.

For Ophthalmic solutions (2 marks)

1- The statement, "Use the solution within a month after opening the container".

2- Name and concentration of preservative if used.

3- The words "NOT FOR INJECTION".

4- Special instructions regarding storage, wherever applicable.

5- A cautionary legend reading as:

Warning: (1 mark)

a- If irritation persists or increases, discontinue the use and consult physician.

b- Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solution.

(d) Define: (each definition 1 mark)

(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) Cannabis (Hemp) : It includes

1) Charas, which is a resin in crude or purified form obtained from the 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 the 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.

(iii) Opium :

It means the coagulated juice of the opium poppy and it's mixture with or without neutral material, (excluding the preparations containing less than 0.2 % of morphine)

(e) Write the procedure for issue of alcoholic preparations from bonded laboratory. (3 marks)

Issue of alcoholic preparation from Bonded Laboratory:

Alcoholic preparations from a bonded laboratory can be taken out by a manufacturer by making an application to the Excise Officer in the prescribed form after paying duty on it. The Excise Officer after checking the entries and realizing the duty payable, allows the required quantities to be removed after issuing a permit. Preparations issued to bonded warehouse or for export or to institutions entitled to receive duty free preparations, may be issued without payment of duty. Instead of paying duty on every consignment, an advance sum may be deposited to the credit of the collecting Government. The licensee is required to maintain accounts in proper forms and

registers. He should also deliver to the officer-in-charge, by the 5th of each months, a return of transaction of business in respect of the preceding month. Supervisory staff for a bonded laboratory is decided by the Excise Commissioner in consultation with the licensee. Excise Officer especially empowered in this behalf, shall inspect the manufactory and submit the report. Dutiable goods cannot be delivered from a bonded manufactory or a bonded warehouse before 6 a.m. and after 6 p.m. nor at any hour on Sundays or other holidays.

The licensee of a bonded manufactory or warehouse shall be held responsible for removal of dutiable goods by any person and shall be liable to be dealt with as if he had removed the good himself.

(f) Discuss offences and penalties under Poisons Act, 1919. (3 marks)

Offences:

1) Unlawful importation of any poison.
2) Unlawful possession & sale of poison.
3) Breaking of any condition of license for import of any poison granted to him

Penalties:-

1) Imprisonment 3 month or with fine- 500 Rs or Both on 1st conviction
2) Imprisonment 6 month or with fine- 1000 Rs or Both on subsequent conviction.
3) The poison in connection with offence, together with the packages, vessels, covering is liable for confiscation.

Q.5. Solve any FOUR of the following : 12

a) Explain general licences and restricted licences under D & C Act,1940

For retail sale two types of licences are issued

1. General licences
2. Restricted licences

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1. **General licences- (1 ½ marks)**

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. General licences are issued for retail & wholesale distribution & sale of drugs & cosmetics for different categories of drugs.

Licences for retail sale of drugs other than those specified in Schedule C,C(1), & X issued in Form No. 20 & for drugs specified in sch. C,C(1) in Form no.21 and for Schedule X drugs in Form 20F.

Conditions-1) In case of 'Pharmacy' a license in Form 20 0r 21 shall be granted only if the requirements prescribed for a Pharmacy in Schedule N have been compiled with. 2)All registers & records maintained, shall be preserved for 2 years from the date of last of entry. 3) Licensee must allow an Drug Inspector to inspect the premises, register & records. 4) The license shall be prominently displayed in part of the premises open to the public.

2. **Restricted licences- (1 ½ marks)**

The licences for the restricted sale of drugs other than those specified Schedule C,C(1) and X and those specified in Schedule C and C(1) 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 firm dealing in drugs, or iii) To a vendor who purchases drugs from a licenced 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& research institutions.

(b) Define "Drug Inspector" and "Govt. Analyst" under Drugs and Cosmetic Act, 1940.

1. **"Drug Inspector" (1 ½ marks)**

   Means-

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

   ii.) In relation to any other drugs or cosmetic, an Inspector appointed by Central or State Government under Section 21 of D & C Act

2. **"Govt. Analyst" (1 ½ marks)**

   Means-

   i.) In relation to Ayurvedic, Siddha or Unani drug, a person appointed by the Central or State Government under Section 33-F; and

   ii.) In relation to any other drugs or cosmetic, a person appointed by Central or State Government under Section 20 of D & C Act.

(c) Explain the duties of pharmacist in relation to his trade as per Code of Ethics.(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 advertisement 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.

(d) What is First Register and give qualification required to enter their name into first register under Pharmacy Act,1948

First register(1 mark)

The Pharmacy Act, 1948 provides for the registration of Pharmacists in all the States of India. As per the Pharmacy Act, 1948, a register has to be maintained containing names of all registered pharmacists. Accordingly each state has to make a register which is called the First Register. The first register is prepared by the concerned State Government and then it is handed over to the State Pharmacy Council. Then the State Pharmacy Council has to maintain the First Register.

Qualifications for entry of name of a person on first register- (2 marks)

A person who has attained age of 18 years, entitled to have his name in first register on payment of prescribed fees & should have the following qualification:-

(i) A degree or diploma in pharmacy, or pharmaceutical chemistry, or chemist or druggist diploma of an Indian University or a State Government or prescribed qualification granted by an authority outside India, or

(ii) A degree of an Indian University other than a degree in Pharmacy or Pharmaceutical chemistry & has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on the prescription of RMP for total period of not less than 3 years, OR

(iii) Has passed an examination recognized as adequate by the State Govt. for compounders & dispensers.

(iv) Has not less than 5 years experience of compounding & dispensing in a hospital or dispensary or other place in which drugs are regularly dispensed on the prescription of RMP.

(e) Which different sale licences(with form number) are required for wholesale and retail sale of drug as per D & C Rules,1945?

Licence issued	**Forms**		
	Drugs other than sch. C, C(1) and X	Drugs Specified in sch. C, C(1)	Drugs specified in sch. X
1 Retail (1 ½ marks)	20	21	20-F
2 Wholesale (1 ½ marks)	20-B	21-B	20-G

(f) State the procedure for dispatch of sample from Drug Inspector to Government Analyst.(3 marks)

1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under subsection(4) of section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18,in an outer cover addressed to the Government Analyst.
2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

Q.6. Solve any FOUR of the following : 16

(a) Give the constitution of Joint State Pharmacy Council. (4 marks)

Joint State Pharmacy Council is constituted as follows:

1) As provided in the agreement not less than 3 and not more than 5 members elected amongst the registered pharmacists of each participating state.

2) As agreement provides, not less than 2 & not more than 4 members nominated by each participating State Governments of whom more than half should possess degree or diploma in pharmacy or pharmaceutical chemistry or be a registered pharmacist.
3) One person elected by the members of each Medical Council from amongst themselves, of each participating state.

The following are ex-officio members:

4) Chief administrative medical officer of each participating state.
5) Officer in-charge of the Drug Control Organization of each participating state
6) Government Analyst appointed under D&C Act, 1940 of each participating state

(b)Define

(i) **Dutiable Goods**: **(2 marks)**

It includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.

(ii) **Toilet Preparations**: **(2 marks)**

The preparation intended to be used in the toilet of human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes..

(c) Discuss Schedule "N" with reference to entrance, premises, furniture, equipments, books and general provisions. (4 marks)

Schedule N-List of Minimum equipments for efficient running of pharmacy:

1) **Entrance:** The front of Pharmacy shall bear an inscription, "Pharmacy".

2) **Premises:** The premises of Pharmacy shall be separate from rooms for private use. The premises shall be well built, dry, well- lit and ventilated and of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in clearly visible and appropriate manner. The area of the section to be used as dispensing department shall not be less than 6 sq.

meters for one pharmacist working there in with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5meters.

The floor of pharmacy shall be smooth & washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable & washable surface devoid of holes, cracks, crevices.

A pharmacy shall be provided with supply of good quality water. There shall be separate dispensing department to prevent the admission of the public.

3) Furniture: A pharmacy shall contain furniture of required size & suitable apparatus. Drugs, chemicals & medicaments shall be kept in a suitable room and suitable containers so as to prevent any deterioration of the contents or of contents of container kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size easily readable with names of medicaments as given in Pharmacopoeias.

A pharmacy shall be provided with dispensing bench having impervious and washable top.

A pharmacy shall be provided with a cupboard with lock and key for storage of poison & shall be clearly marked with "POISON" in red letters on a white background.

Containers of all the concentrated solution shall bear the special labels or marking with the words "To be diluted".

4) Apparatus and Equipment:

A pharmacy shall be provided with following minimum apparatus:

Balance-dispensing, sensitivity30 mg

Balance-counter, capacity 3 kg, sensitivity 1 kg

Beakers, lipped assorted sizes

Corks assorted sizes and toppers

Cork extractor

Evaporating dishes

Filter paper

Funnel –glass

Litmus paper-blue and red

Measuring glass cylinder 10, 25, 50, 100 & 500 ml

Mortar & pestle

Ointment slab, porcelain

Pipettes, graduated, 2ml, 5ml,& 10 ml

Scissors

Spatula, glass rods, thermometer, tripod stand, watch glasses, water distillation still, water bath, weights, wire gauze, pill machine, pill boxes, suppository mould.

5) Books:

The pharmacopoeia (current edition)

National formulary of India (current edition)

The Drugs and Cosmetics Act, 1940 and Rules, 1945

The Pharmacy Act, 1948

Narcotic Drugs & Psychotropic Substances Act, 1985.

6) General Provisions: A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises. The pharmacist shall always put on clean, white overalls. The premises and pharmacy shall be properly kept and everything must be in good order & clean.

All records and registers shall be maintained in accordance with the laws in force. Any container taken from the poison should be replaced therein immediately after use & cupboard is to be locked. The keys of cupboard shall be kept in personal custody of a responsible person.

Medicament when supplied shall have labels conforming to the provisions of the laws in force.

(d) Give offences and penalties under Medical Termination of Pregnancy Act,1971

(4 marks)

As per the latest amendments in M.T.P. Act,1971

i) The termination of a pregnancy by a person who is not a registered medical practitioner shall be an offence punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.

ii) Whoever terminates any pregnancy in a place other than that mentioned in sec.4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.

iii) Any person being owner of a place which is not approved under clause(b) of sec.4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.

(e) Give qualification of Government Analysts per Drugs and Cosmetics Act, 1940.

(4 marks)

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

(ii) A post graduate degree in medicine or science or pharmacy or pharmaceutical chemistry of recognized university with not less than 3 years post graduate experience in the testing of drugs. or

(iii) Associateship Diploma of the Institution of Chemists with 'Analysis of Drugs & Pharmaceuticals 'as one of the subjects with not less than 3 years experience in the testing of drugs in a laboratory under the control of -

-A Government Analyst; or

-Head of an Institution or

- Testing laboratories approved for the purpose by appointing authority

(f) Explain roles of pharmacist in healthcare system.(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 manufactured and distributed.

v) They supply medicines against prescriptions. They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes.

vi) They provide link between Physician & Patient

vii)They are able to advice patients with minor illness

viii)The profession of Pharmacy presently consist of

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

ix)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.