WINTER-15 EXAMINATION

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.

WINTER-15 EXAMINATION

1. Answer any EIGHT of the following: (Each question for 2 marks) 16

a) State the objectives of Pharmacy Act, 1948. (2 marks)

The main objective of Pharmacy Act is to regulate the profession and practice of pharmacy and to raise the status of profession of pharmacy in India.

b) What do Schedule M and Schedule N to Drugs and Cosmetics Act, 1940 Prescribe? (1 mark for each schedule)

Schedule M - Good manufacturing practices & requirements of factory premises, plant, equipment etc. for manufacture of drugs.

Schedule N - List of minimum equipment for the efficient running of a pharmacy.

c) Give the object of Medical Termination of Pregnancy Act, 1971. (2 marks)

This act was passed with the object to provide for the termination of certain pregnancies by Registered Medical Practitioner at approved place for bonafide medical reason & the matters connected therewith.

d) Define 'Magic Remedy' under Drugs and Magic Remedies (O. A.) Act. (2 marks)

Magic Remedy it includes a Talisman, Mantra, Kavacha, and any other charm to possess miraculous powers-

i) For diagnosis, treatment and prevention of any disease in human beings or animals or

ii) For affecting or altering the structure or organic function of the body of human beings or animals.

e) Define 'Registered Pharmacist' as per Pharmacy Act, 1948. (2 marks)

Registered Pharmacist means a person whose name for the time being is entered in the register of the pharmacists of the state in which he is for the time being residing or carrying on his profession or business of pharmacy.

f) Give any two important recommendations of Drugs Enquiry Committee. (2 marks for any 2)

➢ Following are some important recommendations of DEC-

i) Formation of Central Pharmacy Council & State Pharmacy Council which would look after the education & training of professionals.

ii) Creation of Drug Control Department at the Centre with the branches in all the states.

iii) Establishment of well-equipped Central Drug Laboratory (CDL) with expert staff.

iv) Appointment of an advisory board to advise the Govt. in making rules.

v) The drugs industry in India should be developed.

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

vii) Setting of courses for training in pharmacy

viii) Prescribing minimum qualification for registration as pharmacist.

g) Write ex-officio members of Pharmacy Council of India. (2 marks)

i) The Director General of Health Services.

ii) The Drugs Controller of India

iii) The Director of the Central Drugs Laboratory

h) Define 'Drug Inspector' under Drugs and Cosmetics Act, 1940 and Rules. (2 marks)

Drug Inspector means-

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

ii) In relation to any other drugs or cosmetics, a person appointed by the Central or State Government under Section 21

i) Give objectives of DPCO 1995. (½ mark for each point)

➢ This order has been passed with the aim -

i) To achieve adequate production.

ii) To secure or regulate the equitable distribution.

iii) To maintain and increase the supplies of bulk drugs & formulations and

iv) To make these drugs available at fair prices.

j) What is the penalty for contravention in relation to opium poppy? (2 marks)

Whoever in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder, cultivates the opium poppy or produces, manufactures, possesses, sells, purchases, transports, imports inter-state, exports inter-state or uses opium shall be punishable –

1)Where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to six months, or with fine which may extend to ten thousand rupees, or with both;

2) Where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees which may extend to two lakh rupees.

3) In any other case, with rigorous imprisonment which may extend to ten years & with fine which may extends to one lakh rupees.

k) Define 'Lunatic' and 'Minor' under Medical Termination of Pregnancy Act, 1971.

(1 mark for 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.

l) Define 'Toilet Preparation' under Medicinal and Toilet Preparations (E. D.) Act, 1955. (2 marks)

Toilet Preparation- 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..

2. Answer any FOUR of the following: (Each question carries 3 marks) 12

a) Define and differentiate between Law and Ethics. (1 mark for definition & ½ marks for each point any four)

Law- Rules of human conduct binding on all persons in a state or nation.

Ethics - Rules by which a profession regulates actions & sets standards for all its members.

Sr. No.	Law	Ethics
1	Law may prevent one from causing injury to another but it cannot force him to help his neighbor in hours of need.	Helping the neighbor is the function of ethics.
2	A law is something you must obey.	Ethics is how society expects you to behave.
3	Law deals with actions that are punishable.	Ethics deals with right & wrong.
4	Laws are written & approved documents.	Ethics are also written words but they are not carrying legal status.
5	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) What are Education Regulations? (3 marks)

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

- The Education Regulations may prescribe –

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 therein.

v) The equipment and facilities to be provided by the institutions for the students undergoing approved course of study.

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

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

c) Write ex-officio members of DTAB. (3 marks)

i) The Director General of Health Services, who shall be Chairman of the board.

ii) The Drugs Controller of India.

iii) The Director of the Central Drugs Laboratory, Calcutta.

iv) The Director of the Central Research Institute, Kasauli.

v) The Director of Indian Veterinary Research Institute, Izatnagar.

vi) The Director of Central Drug Research Institute, Lucknow.

vii) The President of Medical Council of India.

viii) The President of the Pharmacy Council of India.

d) Give conditions in which name of pharmacist is removed from register, under Pharmacy Act, 1948. (1 mark for each point)

The name of the registered pharmacist can be removed from the register by the Executive Committee, if it is found that

i) His name has been entered by error or on account of misrepresentation or suppression of material fact, or

ii) He has been convicted of any offence or has been guilty of any infamous conduct in any professional respect which in the opinion of the Executive Committee renders him unfit to be kept in the register or

iii) A person employed by him to work under him, in connection with any business of pharmacy has been convicted of any 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.

e) Explain the role of pharmacist in Healthcare system. (3 marks)

1) Pharmacist is legally held responsible for the quality of product which is manufactured and distributed.

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

3)Pharmacists should be responsible for planning & establishment of proper pharmacy services.

4)They provide link between Physician & Patient

5)They are able to advice patients with minor illness

6)The profession of Pharmacy presently consists of -

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

7)Pharmacist has to play an important role in areas such as -

- Prescription adherence.
- Storage and distribution of drugs.
- Consultation and management.
- Drug choice.
- Drug monitoring.
- Information and education.

- Clinical pharmacokinetics.
- Research and development and many other health activities.

f) Define the following under Drugs and Cosmetics Act, 1940: (any three) (1 mark for each definition)

(i) Misbranded Drugs

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) Its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

(ii) Cosmetic

Cosmetic 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.

(iii) Manufacture

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

(iv) Qualified Person

He is person who-

i) Holds a diploma or degree in pharmacy or pharmaceutical chemistry or

ii) Is a registered pharmacist (under Pharmacy Act, 1948) or

iii) Has a minimum 4years experience of dispensing & has been approved by licensing authority as 'Qualified Person' on or before 31st Dec. 1969.

WINTER-15 EXAMINATION

3. Answer any FOUR of the following: 12

a) What are the approved places for medical termination of pregnancy under MTP Act, 1971? Give conditions for approval of places for termination of pregnancies.

Approved places for termination of pregnancy: (1½ mark) The pregnancy may be terminated by RMP only at -

1. A hospital established or maintained by Government
2. A place for the time being approved for the purpose of this Act by the Government.
3. A place approved by 'District Level Committee' (D.L.C.)

Conditions for approval: (1½ marks) The place for the termination of pregnancies shall be approved only if ,

1- The Government is satisfied that the termination of pregnancies may be done under safe and hygienic conditions, and

2- The following facilities are provided –

i. An operation table and instruments for performing abdominal or gynecological surgery.

ii. Anaesthetic equipment, resuscitation equipment and sterilisation equipment.

iii. Drugs and parenteral fluids for emergency use.

b) Give requirements of Bonded Laboratory as per Medicinal & Toilet Preparations Act, 1955.

Requirements of bonded laboratory: (any six points, 3 marks)

1) A Spirit store.
2) Separate room/ rooms for the manufacture of medicinal preparations and toilet preparations.
3) Separate room/ rooms for storage of the finished medicinal preparations and finished toilet preparations.
4) Accommodation near the entrance for the officer-in-charge with necessary furniture.

5) The pipes of sink or wash-basins should be connected with general drainage of the laboratory.

6) The gas and electric connection supply should be such that their supply can be cut-off at the end of day's work.

7) Every room should bear a board indicating the name of room and serial numbers.

8) Every window would be provided with specific arrangements of malleable iron rods of prescribed dimensions and window should be covered on the inside with strong wire netting of mesh not exceeding 25mm.

9) There shall be only one entrance to the laboratory and one door to each of its compartments. All the doors shall be secured with excise ticket locks in the absence of officer in-charge.

10) All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial numbers and full capacity.

11) The vessels for storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks.

c) Write offences and penalties under Drugs and Magic Remedies Act, 1954.

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

Offence- 1) Contravention of any of the provision of this Act or Rules-

Penalties: Imprisonment 6 month or with fine or with both on 1st conviction.

Imprisonment 1 year or with fine or with both on subsequent conviction **(1 ½ mark)**

Offence-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

(1 ½ mark)

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.

d) Discuss the provisions to control possession for sale and sale of poisons.

Possession & sale of specified poisons: **(any 6 points, 3 marks)**

The State Govt. may regulate the possession & sale of poison within the state. The sale may be wholesale or retail. The rules may be applicable for the whole or any part of the territories under the administration of the state.

Such a rules may provide for-

i) Grant of licenses for the possession of any specified poison for sale, either wholesale or retail.

ii) Fixing of fees to be charged for such a licenses

iii) The classes of persons to whom the licenses for the possession & sale of poisons are to be granted

iv) The classes of persons to whom such poisons are to be sold.

v) Maintenance of Register for the sale of poisons & inspection of the same.

vi) Safe custody of poisons & the labeling of the vessel, coverings or packages in which such poison is sold or stored for sale.

vii) Inspection & Examination of any such poison possessed for sale by any vendor

e) Which operations are to be permitted and regulated by Central Government under Narcotic Drugs and Psychotropic Substances Act, 1985?

Operations permitted & regulated by Central government under N.D.P.S. Act, 1985 (any 6 points, 3 marks)

i) The cultivation, or gathering of any portion of coca plant (only on account of the Central Government), or the production, sale, purchase, transport, import inter-state, export inter-state, use or consumption of coca leaves.

ii) The cultivation of the opium poppy;(only on account of Central Government)

iii) The production & manufacture of opium & production of poppy straw

iv) The sale of opium & opium derivatives from the Central Government factories for export from India or sale to State Government or to manufacturing chemists.

v) The manufacture of manufactured drugs (other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.

vi) The manufacture, possession, transport, sale, purchase, import inter-state, export inter-state, use or consumption of psychotropic substances

vii) The import into India & export from India & transshipment of narcotic drugs & psychotropic substances

f) Give functions of Central Drugs Laboratory (any 6).

Functions of Central Drug Laboratory (CDL) (6 points, 3 marks)

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

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

iii) 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

iv) 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

v) 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

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

4. Answer any FOUR of the following: 12

a) Define the following under NDPS Act, 1985 (any three): (each definition carries 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). **Addict**: A person habitual to regular use of any narcotic drug or psychotropic substance is known as addict.

iii). **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).

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.

b) Define 'bulk drug' and 'ceiling price' under Drugs (Prices Control) Order, 1995.

Bulk drug :- (2 marks) It means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereoisomers and derivatives conforming to pharmacopeial 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.

Ceiling price: (1 mark) It means a price fixed by the Government for scheduled formulations according to the provisions of DPCO.

c) Explain offences and penalties under Poisons Act, 1919.

Offences and penalties under Poisons Act, 1919:

Offences: (1 ½ marks)

Unlawful importation of any poison.

Unlawful possession & sale of poison.

Breaking any condition of license for import of any poison.

Penalties:- (1 ½ marks)

Imprisonment 3 month or with fine- 500 Rs or both on 1st conviction

Imprisonment 6 month or with fine- 1000 Rs or both on subsequent conviction.

The poison in connection with offence together with the packages, covering is liable for confiscation.

d) Which different instructions and warnings should appear on the label of ophthalmic preparations?

Instructions on the label of ophthalmic solutions & suspensions – (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

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.

Ophthalmic ointments (1 mark)

1 Special instructions regarding storage wherever applicable

2 Warning:- If irritation persists or increases, discontinue the use and consult physician

e) Give classes of prohibited advertisement under Drugs and Magic Remedies (O.A) Act and Rules.

Classes of prohibited advertisements under Drugs & Magic Remedies Act and Rules: (any 3 classes, 3 marks)

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 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.

II) Advertisement of Magic Remedies for treatment of certain diseases or disorders which may claim to be efficacious for any of the purposes specified in I as above.

III) 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 particularly.

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

IV) Prohibition of advertisements of Magic Remedies for the treatment of certain diseases – Publication of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited

f) Write duties of drug inspector in relation to sale of drugs and cosmetics.

Duties of Drug Inspectors in relation to sale of drugs and cosmetics-(any 6 points, 3 marks)

1) To inspect at least twice a year all establishments licensed for sale of drugs in the area assigned to him and to check whether the conditions of the licenses are observed or not.
2) If he thinks necessary, to obtain and send the samples of imported drugs and cosmetics for test or analysis, which are being sold or stocked in contravention of the provisions of the Act.
3) To investigate any complaint in writing made to him.
4) To institute prosecutions in case of breach of the Act and Rules.
5) To maintain the records relating to all inspections and actions taken by him and to submit copies of such records to the controlling authority.
6) To make inquiries and inspections regarding the sale of drugs in contravention of the provisions of the Act.
7) To detain the imported packages, if he suspects to contain drugs, the import of which is prohibited.

Q. No 5 Answer any FOUR of the following: (Each question carries 3 marks) 12

a) Write the formula for the calculation of 'Retail Price' of drug formulations and explain terms involved under it.

(1 mark for formula, 2 marks for terms)

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) + ED

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.

b) What qualifications will entitle a person to be appointed as government analyst?

(Each point carries 1 Mark)

(i) A graduate in medicine or science or pharmacy or pharmaceutical chemistry of 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(India) 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.

c) Explain role of 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 practiced & 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 contain:

(i) Misleading or exaggerated statements,

(ii) A guarantee of therapeutic efficiency,

(iii) An offer to refund money paid

(iv) An appeal to fear

(v) The word 'cure' in reference to an ailments or symptoms of ill-health.

d) List licenses (with form numbers) for retail sale and wholesale of schedule C, C1 and schedule X drugs.

(½ Mark for each form number)

Licenses mainly issued in following form no. for retail and wholesale of Schedule C, C1, & Schedule X drugs

Sr. No	License issued	Forms		
		Drugs specified in schedule C	Drugs specified in schedule C1	Drugs specified in schedule X
1	Retail	21	21	20-F
2	Wholesale	21-B	21-B	20-G

e) Write procedure for approval of institute 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, deputes 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 the reports of the inspector if council is satisfied, that the course or examination under consideration is in conformity with ER, 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.

f) Define 'Adulterated drugs' under Drugs and cosmetics Act, 1940.

(½ Mark for each point)

A drug shall be deemed to be 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 whereby 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 color other than prescribed which may be used for the purpose of coloring 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. No 6 Answer any FOUR of the following: (each question carries 4 marks) 16

a) Explain the procedure taken by drug inspector for taking samples from manufacturing premises. (One mark for each step)

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)
3. Divide the sample in the presence of such person in three parts unless he willfully absents himself and effectively seals and mark the portions so sealed.
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 sample.
   d) Send remaining portion to a warrantor, if any, (whose name, address and other particulars have been disclosed)

b) Write functions of Pharmacy Council of India.

(One mark for each point any four)

Functions of PCI:-

1) To prescribe the minimum standard of education required for qualification as a Pharmacist. (This can be provided by making rules as Education Regulation which prescribes minimum qualification for admission, duration of course, details of syllabus, practical training,& examination, minimum facilities required for the conduct of course, examination & practical training)

2) To regulate the minimum educational standard (For this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy & report on the facilities available & decides whether the institution should be recognized or not)

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

4) To compile & maintain a Central Register for Pharmacist containing names of all persons for the time being entered in the state register.

5) Any other functions that may be assigned to the Central Council in the furtherance of the objective of the Pharmacy Act,1948.

c) Discuss the circumstances under which pregnancies may be terminated by registered medical practitioner.

(One mark for consent, two marks for the Duration of pregnancies and one mark for other cases)

1) Consent:-

No pregnancy shall be terminated by a RMP without the consent of the pregnant women except :

i) When the pregnant woman is less than 18 yrs. of age or

ii) The pregnant woman is lunatic.

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

2) Duration of pregnancies:

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 & not less than 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.

3) Other cases:-

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.

d) Write offences and penalties under Pharmacy Act, 1948.

(One mark for each offence and penalty)

1. Offences: **Falsely claiming to be Registered Pharmacist**:

Penalties: 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. Offences: **Dispensing by unregistered persons**:

Penalties: 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. Offences: **Failure to surrender certificate of registration**:

Penalties: Is also punishable with fine upto fifty rupees.

4. Offences: **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.

e) Give general requirement of labeling of drugs as per D& C Act, 1940.

(Each point carries ½ marks)

i)Name of the drug :- 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) Content of active ingredients expressed in terms of:-

- For oral liquids the quantities may be expressed per 5ml or multiples thereof,
- 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(1) the expiry date.

viii)Free sample to the medical profession – "Physician's sample – Not to be sold'.

ix)Alcoholic preparations containing more than 3 per cent by volume of alcohol shall bear on the label statement showing the quantity of alcohol in terms of average percentage by volume in the finished product.

f) As per code of ethics, discuss the role of pharmacist in relation to job. (4 marks)

1. Pharmaceutical services:

i) Provide efficient and reasonably comprehensive pharmaceutical services.

ii) Such services should include supply of commonly required medicines without undue delay and furnishing the emergency supply at all times.

2. Pharmacy/Drug Store:

i) A qualified pharmacist required to control pharmacy activity.

ii) A pharmacy should be planned in such a way that there is no accidental contamination in the preparation, dispensing and supply of medicines.

iii) The appearance of premises should reflect the professional character of pharmacy.

3. Prescriptions:

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

ii) A pharmacist should not show any expression on his face after receiving the R_x.

iii) No addition, omission or substitution of ingredients in a R_x should be made without the consent of prescriber whenever possible except in an emergency.

iv) In case of error, R_x should be referred back to the prescriber for necessary correction.

v) If at all change in R_x is necessary, it should not affect the reputation of physician.

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

4. Drugs/Ingredients:

i) While dispensing, the drugs or ingredients should be weighed or measured correctly.

ii) Pharmacist should always use drugs and medicinal preparations of standard quality.

iii) Drugs likely to cause addiction or abuse should not be supplied when there is reason to suppose that it is required for such purpose.

5. Practical Training:

i) While imparting training, the in-charge pharmacist should see that the trainees acquire sufficient technique and skill.

ii) No certificate should be granted to the trainee pharmacist before completion of prescribed period of training or without undergoing practical training or unless the trainee acquires sufficient knowledge.