SUMMER-16 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.

1. Answer any EIGHT of the following: (8 X 2 Marks) 16

a) Give the objective of the Drugs And Magic Remedies (OA)Act, 1954

(2marks)

The Drugs and Magic Remedies Act passed with following main object:

i) To control certain types of advertisement related to drugs.

ii) To prohibit certain kinds of advertisements relating to magic remedies; which falsely claim and mislead the public, and

iii) To provide for matters related therewith.

b) What are the ethics to be remembered by pharmacist during handling of drugs?

(2 marks)

i) While dispensing the prescription, the drugs or ingredients must be weighed or measured correctly as the case may be by scales or measures.

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

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

c) State in brief different operations which are permitted and regulated by the State Government under NDPS Act, 1985 and rules.(any four)

(1/2 mark for each point, any four points)

Subject to provisions of section -8 following operations are permitted and regulated by the State Government-

i) Possession, transport, interstate import, interstate export, warehousing, sale, purchase, consumption and use of poppy straw.

ii) Possession, transport, interstate, export interstate, warehousing, sale, purchase, consumption, and use of opium.

iii) Cultivation of any cannabis plant, production, manufacture, possession, transport, import interstate, export interstate, sale, purchase, consumption, or use of cannabis (excluding charas);

iv) Manufacture of medicinal opium, or any preparation containing any manufactured drug, which maker is lawfully possessing.

v)Possession, transport, purchase, sale, import interstate, export interstate, use or consumption of manufactured drugs (other than prepared opium and of coca leaf) and any preparation containing any manufactured drug.

vi)Manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the state government for his personal consumption on medical advice.

d) Define Net worth under DPCO, 1995.

Net worth (2 Marks) -It means the paid-up share capital of a company plus free reserve, if any and surpluses excluding outside investment which are not readily available for operational activity.

e) Write objectives of the Drugs and Cosmetics Act, 1940. (1/2 mark for each point)

The Drug and Cosmetics act was passed in 1940 with main object

i) To regulate the import, manufacture, distribution, and sale of Drugs and Cosmetics.

ii) To regulates the manufacture by making the provisions, and rules, which provides control over the manufacture of spurious or sub- standard drug in the country.

iii) To provides for the control over the sale & distribution of drugs by only trained & qualified persons.

iv) To provide for the control over the manufacture, sale and distribution of Ayurvedic, Siddha, Unani and Homoepathic drugs.

f) Give the penalties for contravention under poison act 1919. (2 marks)

Offences:

Unlawful importation of any poison.

Unlawful possession & sale of poison.

Breaking any condition of license for import of any poison.

Penalties:-

Imprisonment 3 month or with fine- 500 rupees or with Both on first conviction

Imprisonment 6 month or with fine- 1000 rupees or with Both on subsequent conviction.

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

g) Define the term 'Repacking of Drugs' under D&C act, 1940 and rules. (2 Marks)

It is the process of breaking up any drug from a bulk container into small packages and the labeling of each such package with a view to its sale and distribution. But, it does not include the compounding, dispensing or the packing of any drug in the ordinary course of retail business.

h) Define under MTP Act, 1971- (1 Mark for each Definition)

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

(ii) Guardian :- A person having the care of a minor or a lunatic. OR
person having the care of the 'person of minor' or a 'mentally ill person'

i) Give the functions of the 'Pharmacy Council of India' under Pharmacy Act, 1948 (any two) (1 mark for each point, any two points)

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 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.

j) Give objective of Poison Act, 1919. (2 Marks)

i) To regulate & control import, possession & sale of poisons.

ii) 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) Define under the Medicinal and Toilet Preparation (ED) Act, 1955

(i) Dutiable goods (1Mark)

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

(ii) Restricted Preparations. (1 Mark)

These are medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages.

l) Differentiate between 'Law' & 'Ethics' (any two points)

(1 Mark for each point, any two 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 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 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.

2. Answer any FOUR of the following (4 X 3 Marks) 12

a) Write in brief about the objectives and scope of pharmaceutical legislation in India.

Objectives- (any 3 points, $1^{1/2}$ marks)

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

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

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

4) To regulate the profession of pharmacy.

5) To promote the Indigenous research technology

Scope of pharmaceutical legislation of India (any 3 points, $1^{1/2}$ marks)

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

2) 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.

3) It helps the pharmacist to understand their legal & ethical responsibilities & their by avoid the danger of unnecessary legal proceedings.

4) The patient should get the drugs of good quality which are tested & evaluated for

safety purpose.

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

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

b) Give the formula for calculation of retail price of formulation as per DPCO, 1995. Explain each term used in the formula.

(1 Mark for the formula, 2 Marks for explanation)

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.

c) What rule are made to control the possession for the sale and sale of specified poison? (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 licenses for the possession for sale, either wholesale or retail of any specified poison and fixing of fees to be charged for licenses.
2. The classes of persons to whom the licenses 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.

d) What are schedule 'J' and schedule 'H' to the D & C rules prescribed? Give examples of each(any two examples)

(1 ½ Marks for each schedule and e.g.)

Schedule J:- List of diseases and aliments which a drug may not claim to prevent or cure **e.g.** Appendicitis, blindness, cataract, dropsy, epilepsy, heart diseases, leprosy, obesity, lupus. (any disease mentioned under Schedule J)

Schedule H: (1 mark) - Prescription drugs which are required to be sold by retail only on prescription of Registered Medical Practitioner. **e.g**. Analgin, Azathioprine Bupivacaine, Clotrimazole, Disulfiram. (any drug mentioned under Schedule H)

e) Give the constitution and functions of Drug Consultative Committee.

(2 Marks for constitution and 1 Mark for function)

Constitution of Drug Consultative Committee:- it consist of

1. Two representatives of Central Government nominated by Central Government and
2. One representative of each State Government nominated by the concerned Government.

Functions of Drug Consultative Committee:- This is an advisory committee founded by Central Government to advice the Central Government, State Government and Drug Technical Advisory Board on any matter to secure uniformity throughout India in the administration of this Act.

f) Define under D & C act, 1940 & rules

(1½ Marks for each Definition)

(i) Cosmetics:- 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.

(ii)Drug Inspector :-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

Q. 3. Answer any FOUR of the following **12**

(a) Define 'Advertisement' and 'Magic Remedy' under Drugs & Magic Remedies (OA) Act, 1954. (each definition $1^{1/2}$ marks)

Advertisement: It includes

i) Any notice, circular, label, wrapper or otherwise such document, and

ii) Any announcement made orally or by means of producing or transmitting light, sound or smoke.

Magic Remedy: It includes a Talisman, Mantra, Kavacha, and any other charm claiming 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 or animals.

(b) Give the classes of advertisements which are prohibited under Drug and Magic Remedies (OA) Act, 1954 (Any three classes). (1 mark for each class, any 3)

Classes of prohibited advertisements under Drugs & Magic Remedies Act and Rules:

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 which may claim 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 particularly.

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

4) 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

(c) How pharmacist is a link between Medical Profession and Public? Explain as per pharmaceutical code of Ethics. (3 marks)

i) He should be constantly in touch with the modern developments in pharmacy by regularly reading books, journals, magazines.

ii) He should be expert in the field of pharmacy so that he may advice the physician on pharmaceutical matters.

iii) He may be able to educate the people for maintaining healthy and sanitary conditions of living.

iv) Pharmacist should neither discuss physician's prescriptions with customers nor disclose to them the composition of prescriptions.

(d) How a pharmacist should handle the prescription according to the pharmaceutical ethics? (½ marks for each point)

Handling of prescription-

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

ii) After receiving the prescriptions, a pharmacist should not even show any expression on his face so that the patients will lose their faith in the physicians or prescribers .

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

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

v) If at all change in prescription is necessary in the interest of the health of the patient, it should not affect the reputation of the physician.

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

(e) Give the object of N. D. P. S. Act, 1985 and define 'Coca derivatives' under NDPS Act, 1985.

The main object of this Act is- (1 ½ Marks)

i) To consolidate & amend law relating to Narcotic Drugs

ii) To make strict provision to prohibit, control & regulate the operations relating to Narcotic Drugs & Psychotropic Substances

iii) To provide for matters connected therewith.

Definition of Coca Derivative - (1 ½ Marks)

Coca Derivative means-

i) Crude cocaine which can be used directly or indirectly for the manufacture of cocaine.

ii) Ecgonine and all the derivatives from which it can be recovered.

iii) Cocaine, which is methyl ester of benzoyl- ecgonine and its salts.

iv) Preparations containing more than 0.1 percent of cocaine.

(f) What is the penalty for illegal possession or use of 'small quantity' of narcotic drug as per NDPS Act, 1985? (3 marks)

As per the latest amendments -

Whoever consumes any narcotic drug or psychotropic substance shall be punishable -

i) Where the narcotic drug or psychotropic substance consumed is cocaine, morphine, diacetyl-morphine or any other narcotic drug or any psychotropic substance as may be specified in this behalf by the Central Government by notification in the Official Gazette, with rigorous imprisonment for a term which may extend to 1 year, or with fine which may extend to twenty thousand rupees, or with both; and

ii) Where the narcotic drug or psychotropic substance consumed is other than those specified in or under clause (a) with imprisonment for a term which may extend to six months, or with fine which may extend to ten thousand rupees or with both.

Q. 4. Answer any FOUR of the following **12**

(a) Define the following under NDPS Act, 1985:

(i) Medicinal Hemp: It is any extract or tincture of cannabis. **(1 Mark)**

(ii) Opium: (1 mark) 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)

(iii) Coca leaf – It includes **(1 Mark)**

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

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

(b) Give the constitution of State Pharmacy Council under 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 persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or be a registered pharmacists.
3) One member elected by the members of Medical Council of the State amongst themselves.

The following are the ex-officio members:

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

(c) Define under DPCO, 1995- (Each definition 1 ½ marks)

(i) Free reserve- means a reserve created by appropriation of profits, but does not include reserves provided for contingent liability, disputed claims, goodwill, revaluation and other similar reserves.

(ii) Formulation-

means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but it does not include -

(a) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.

(b) any medicine included in the Homeopathic system of medicine; and

(c) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

(d) Explain essential requirements for Bonded Laboratory.

Requirements of bonded laboratory: (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

(e) Give the procedure to be followed for the movement of goods from one warehouse to another under MTP Act, 1955. (3 marks)

Procedure for the movement of goods from one warehouse to another-

i) When the goods are to be removed from one warehouse to another, the consignor or the consignee should enter into a bond with surety or sufficient security.

ii) Such bond shall be furnished to the officer-in-charge of the warehouse of removal or the warehouse of destination as the case may be.

iii) Such bond shall remain valid until officer-in-charge of the warehouse of removal has received a re-warehousing certificate (stating that the goods have been re-warehoused) form the officer-in-charge of warehouse of destination.

iv) The consignor should make an application in triplicate for removal of goods from one warehouse to another warehouse to the officer-in-charge of the warehouse together with other necessary information as the Excise Commissioner may require at least 24 hours before the removal of goods.

v)The officer-in-charge shall take account of the goods and send the duplicate copy after giving remark for removal to the officer-in-charge of the warehouse of destination. And the triplicate shall be given to the consignor for dispatch to the consignee.

vi) On arrival of the goods at the warehouse of destination, the consignee should present them such goods along with the triplicate application and the transport permit to the office-in-charge.

vii) Then he shall take account of the goods & complete the re-warehousing certificate on the duplicate and the triplicate application and return the duplicate to the officer-in-charge of the warehouse of removal and the triplicate to the consignee for the dispatch to the consignor.

viii)The consignor shall present such triplicate copy of the application with the warehousing certificate to the officer-in-charge of his within 90 days of the issue of the transport permit to him.

(f) Give 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 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. **(1 ½ mark)**

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

a) List the facilities provided for and 'Approval of places for termination of pregnancy'.

Facilities :- (2 marks)

Upto 12 weeks MTP : Places may be approved with following facilities :{Rule-5(l) (ii)}

.Gynaecology Examination Table/ Labour Table,

. Resuscitation and Sterilisation equipment,

.Drugs & Parental Fluids,

.Backup facilities for treatment of shock, &

. Facilities for Transportation.

Upto 20 weeks MTP :Places may be approved with following facilities :{Rule-5(l) (ii)a,b,c}

i. An operation table and
ii. instruments for performing abdominal or Gynecological surgery.
iii. Anaesthetic Equipments, Resuscitation and Sterilisation equipment.
iv. Drugs and parenteral fluids for emergency use, as notified by Government of India from time to time

Approved places for termination of pregnancy: (1 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.)

b) Explain circumstances under which RMP can terminate pregnancy under MTP Act, 1971 and Rules.

(One mark for consent, one mark 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.

c) Give three offences and penalties for the same under MTP Act, 1971.(each point 1 mark)

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.

d) Give the objectives of Pharmacy Act, 1948 and give ex-officio members of PCI.
(objectives 1 ½ marks, ex-officio members 1 ½ marks)

The main objective of Pharmacy Act is-

i)To regulate the profession and practice of pharmacy and

ii) To raise the status of profession of pharmacy in India.

Ex-officio members of PCI:

i)The Director General of Health Services.

ii)The Drugs Controller of India

iii)The Director of the Central Drugs Laboratory

e) Define under Pharmacy Act, 1948-

i) Registered pharmacist: (2 marks) 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.

ii) Central Register: (1 mark) Register of pharmacists maintained by the Central Council.

f) What qualifications will entitle to a person to have his name on the First Register? (all points, 3 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.

Q. No 6 Answer any FOUR of the following: (each question carries 4 marks) 16

a) What are the powers of Drug Inspectors appointed under Drugs and Cosmetics Act, 1940? (all points, 4 marks)

Within the local limits for which the Inspector is appointed, he may,

i)Inspect:

1) Any premises wherein any drug or cosmetic is being manufactures. And also he may inspect the means employed for standardizing and testing the drug or cosmetic.

2) Any premises wherein any drug or cosmetic is being sold or stocked or exhibited or offered for sale of distributed.

ii)Take samples of any drug or cosmetic

1) Which is being manufactures or being sold or is stocked or offered for sale or exhibited or being distributed.

2) From any person conveying, delivering or preparing to deliver any drug or cosmetic to a purchaser or a consignee.

iii) Search any person in connection with the offence under this chapter at all reasonable times.

iv) Enter and search at all reasonable times, any place or premises in which he has reason to believe that an offence is being committed or has been committed.

v) Stop and search any vehicle or other conveyance which he has reason to believe used for carrying any drug or cosmetic in respect of which offence has been or is being committed.

vi) Give order in writing to the person in possession of drug or cosmetic in respect of which offence has been committed or is being committed, not to dispose stock of such drug or cosmetic for a specified period not exceeding twenty days or unless the defect may be removed by the possessor of the drug or cosmetic, and may seize the stock of such drug or cosmetic or any substance or article used to carry drug.

vii)Examine any record, register, document or any other material object found while exercising above powers and seize the same if he has reason to believe that it is an evidence of the commission of an offence under the Act.

viii) Exercise any other powers as may be necessary, for carrying out the purpose of this Act and the rules thereunder.

b) Give the functions of:

i) Narcotic Commissioner of State: (3 marks)

1) Supervision of cultivation of the opium poppy

2) Production of opium

3) Other functions as may be entrusted to him by the Central Government.

ii) Narcotic Drugs and Psychotropic substances consultative committee: (1 mark) The committee shall advise the Central Government on the matters relating to the administration of this Act.

c) Give any two offences and penalties for the same under Medicinal and Toilet Preparations Act, 1955. (2 marks for each offence and penalty, any 2)

Offence-

1) a) Contravention of any of the provisions relating to the terms & conditions of a license granted under the Act, or

b) Failure to pay any duty of excise payable under this Act, or

c) Failure to supply required information or supplying false information or

d) Attempt to commit or abet any of the above offence

Penalty- Imprisonment upto 6 month or Fine upto 2000/- or both

2)Connivance by any owner or occupier of land or by any agent of such owner or occupier for any offence against the provision of this Act, or rules there under.

Penalty- Imprisonment upto 6 month or Fine upto 500/- or both for every offence

3)Vexations search, seizure by any officer exercising powers under this Act or rules there under

Penalty- Fine upto 2000/-

4)Refusal to perform or withdrawal of oneself from duty by the Excise Officer without permission of the superior officer.

Penalty - Imprisonment upto 3 month or Fine upto three months pay

5)Failure to furnish proof of export within the prescribed period to the satisfaction of Excise Commissioner by any persons authorised to export dutiable goods in bond.

Penalty- Fine upto 2000/- extend to twice the amount of duty

6)Of all the offences committed with respect to warehousing

Penalty- Fine upto 2000/- & goods related to the offences are liable for confiscation

7)Obstruction to the officers while exercising their powers regarding Entry, Search & Seizure

Penalty- Fine upto 500/-

8)Prosecution:- Only the sub-inspector or officer above his rank can institute the prosecution under this act

9)Arrests: - Only the sub-inspector or officer above his rank can make arrest under this Act.

10)A breach of the rules, where no punishment is provided.

Penalty- Fine upto 1000/- & confiscation of the goods

11)Keeping of stocks of dutiable goods in disorderly manner (not in accordance with the provision of this Act.)

Penalty- Fine upto Rs. 1000/-

12)Maintaining false accounts of stock of goods in a manufactory or warehouse or not

following the provision of this Act while maintaining such accounts

Penalty- Fine upto Rs. 2000/-

13)Sale of dutiable good except in prescribed containers bearing a label.

Penalty- Fine upto 1000/- & confiscation of the goods related with this offence.

14)Disclosure of information by Excise officers learned by him in his official capacity.

Penalty- Fine upto 1000/-

d) Give conditions to be observed by a person to whom granted a restricted license for sale of drugs. (4 marks)

1. The licensing authority should satisfy that the premises in respect of which license is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs.

2. The license shall be displayed in a prominent place of the premises, open to the public or kept with vendor who shall produce it on demand by Inspector or by authorized officer in this behalf.

3. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

4. No drug shall be sold unless such drug is purchased under cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

5. The licensee shall inform Licensing Authority in writing any change in the constitution of firm operating under the license. From a date on which such change takes place, current license deemed to be valid for a maximum period of three months. In the meantime a fresh license has to be taken from the Licensing Authority in the name of the firm with changed constitution.

6. The licensee who is issued a license in Form - 21A shall deal only in such drugs as can be sold without supervision of a ‘qualified person’.

e) Describe the general labeling conditions of drugs under D & C Act, 1940. (all points, 4 marks)

i)Name of the drug :- Proper name of the drug shall be printed in a more conspicuous manner than the trade name, if any, which shall appear just after or under proper name. The proper name shall be the name specified in schedule F or F(1) or the names specified in the books of standards or in a schedule to the rules or in the international standard prescribed by agencies like W.H.O .

ii) Statement of net contents: in terms of weight, volume or number of units of contents, number of units of activity 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,
- For liquid parenterals- content per milliliter or as percentage by volume or content per dose ,
- In solid drugs for parenteral use the quantities may be given as units or weight per gram or milligram,
- For tablets, capsules, pills etc.: content per tablet/ capsule/pill, etc.
- 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: The name of the manufacturer & address of the premises of the manufacture where the drug has been manufactured.

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 : Every drug manufactured for sale bear on its label date of manufacture

viii) Date of expiry of potency : Drugs specified in schedule P and schedule C(1), shall bear an label ‘expiry date’. Expiry date shall not exceed the period specified in schedule P Or as fixed

by licensing authority in case of schedule C(1) drugs. Where such drugs are imported, they shall bear import license number, preceded by 'Import License'

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) Give qualification of 'Govt Analyst" under D & C Act, 1940. (all points, 4 marks)

(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.