SUMMER– 14 EXAMINATION

Subject Code: **0814** **Model Answer** Page No:01/31

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.

SUMMER – 14 EXAMINATION

Q1 Answer any EIGHT of the following

a) Define Law and Ethics

Law is defined as follows **(1 mark)**

i. Law is a philosophically discovered set of principles which expresses true nature of things and to which man must conform his conduct.
ii. Or Law is a body of agreements of men organized politically into society.
iii. Or Law is a body of commands of sovereign authority in a politically organized society.
iv. Or Law is a system of percepts whereby an individual may realize the most complete freedom consistent with like freedom of others.
v. Or Law is an impediment to natural rights and natural liberty.
vi. Or Law is divinely ordained set of rules.
vii. Or Law is the tradition of old customs which have proved acceptable to God.
viii. Or Law is the wisdom of wisemen who learnt safe course of action.
ix. Or Law is a system of rules imposed upon a society by the dominant class in furtherance of its own interests.
x. Or Law is a rules of human conduct binding on all persons in a state or nation.

Ethics is defined as follows **(1 mark)**

i. Ethics is the science of moral principles and represents a slightly different kind of effort to control human conduct
ii. Or Ethics is an appeal to the conscience and more often than not, it helps the people in trading right paths in all walks of life.
iii. Or Ethics is rules by which a profession regulates actions and sets standards for all its members.

b) Objective of N.D.P.S. Act, 1985 (2 marks)

The main objective of N.D.P.S. Act, 1985 was enacted-

- To consolidate and amend the existing laws relating to narcotic drugs.
- To make strict provision to prohibit, control & regulate the operations relating to Narcotic Drugs & Psychotropic Substances
- To strengthen the existing controls over drugs of abuse.
- To enhance the penalties for trafficking offences.
- To provide matter connected therewith

c) 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 Pharmacist of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy.

d) What Schedule H and Schedule G prescribe as per as D & C Act?

- Schedule H : **(1 mark)** - Prescription drugs which are required to be sold by retail only on prescription of Registered Medical Practitioner.
- Schedule G: **(1 mark)** - List of substances that are required to be taken only under supervision of Registered Medical Practitioner

  The drugs to be labeled with the words caution: It is dangerous to take this preparation except under medical supervision.

e) **Define Drug Inspector as per as D & C Act, 1940. (2 marks)**

Means:

(a) In relation to Ayurvedic, Siddha or Unani drugs, an Inspector appointed by Central, Or State Government under section 33 -G;

(b) In relation to any other drugs or cosmetics an Inspector appointed by Central, Or State Government under section 21

f) What is the penalty for allowing premises etc. to be used for commencement of an offence as per as NDPS Act? (2 marks)

Penalty for allowing premises to be used for commencement of an offence under NDPS Act is Rigorous imprisonment of not less than 10years which may extend to 20 years and a fine not less than 1 lakh which may extend to 2 lakh rupees or the court so feels in excess of Rs. 2 lakh rupees

g) What is the provision for sale of split quantities of formulations as per as DPCO Act? (2 marks)

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

h) Give the classification of Medicinal and Toilet preparations containing alcohol as per as Medicinal and Toilet preparations (Excise duties) Act (2 marks)

The classification of Medicinal and Toilet preparations containing alcohol as per as

(A) Allopathic preparations

i) Official Allopathic Preparations

ii) Non Official Preparations (Patent and Proprietary Preparations)

(B) Homeopathic Preparations

(C) Ayurvedic Preparations

Medicinal and Toilet Preparations are also classified as

(i) Restricted Preparations

(ii) Un-restricted Preparations.

i) Write the objective of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. (2 marks)

objective-

i) To control certain types of advertisements relating to drugs &

ii) To prohibit certain kinds of advertisement relating to Magic Remedies, which falsely claim & mislead public.

iii) To provide matter related therewith.

j) Give the objective of Poisons Act, 1919. (2 marks)

The Poison act, 1919 was passed with an objective-

- To control and regulate the possession, import, sale of poisons.
- The Central Government under this Act holds the authority to regulate the import of poisons across any of the defined custom frontiers and the State Government has the authority to make the rules regarding the possession of poison along with its sales.

k) Define Registered Medical Practitioner as per M.T.P Act, 1971.(2 marks)

Registered Medical Practitioner- A medical practitioner who possesses any recognized medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 whose name has been entered in a State Medical Register & who has such experience or training in gynecology & obstetrics as the case may be prescribed by rules under this Act.

l) What is the purpose of Pharmaceutical Legislation (2 marks)

The purpose of Pharmaceutical Legislation is -

To ensure that the patients receive drugs of required quality, tested and evaluated for safety efficacy for their intended use. It is associated with the health of the society.

Q2) Answer any FOUR of the following: (each question carries 3 marks) 12 marks

a) Write the offences and penalties as per as 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 with Both on first conviction

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

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

b) Write any three offences and penalties as per medicinal and toilet preparations (excise Duties) Act, 1955 (3 marks) (Any three offences, each offence 1 mark)

Offences-

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 one self from duty by the excise officer without permission of the superior officer.

   Penalty - Imprisonment upto 3 month or Fine

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/-

c) Define-(each definition 1.5 mark)

Free Reserve- It is defined as a reserve created by appropriation of profits but does not include reserves provided for contingent liability, disputed claims, goodwill, revaluation & other similar reserves

Net worth- It is defined as Paid up share capital of company plus free reserve, if any and surpluses excluding outside investment which are not readily available for operational activity.

d) The measures for preventing and combating abuse of narcotic drugs and illicit traffic as per NDPS act, 1985 is carried in the following manner- (Any three measures, each measure 1 mark)

Central Government under the provisions of this Act, may take the measures with respect to all or any of the following matters :-

i. Co-ordination of actions by various officers, State Government and other authorities under this act or under any other law for the time being in force relating to enactment of the Act.
ii. Obligations under the international conventions.
iii. Assistance to the concerned authorities in foreign countries and concerned international organizations regarding prevention and suppression of illicit traffic n narcotic drugs and psychotropic substances.
iv. Controlling the abuse of narcotic drugs and psychotropic substances.
v. Identifying, treating, rehabilitation, education and social re-interaction of addicts.
vi. Supplying drugs to addicts where such supply is a medical necessity.
vii. Such other matters for effective implementation of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.

e) Ex-officio members of Drug Technical Advisory Board are as follows-(3 marks)

i. Director-General of Health services, who is also the Chairman.
ii. The Drugs Controller of India.
iii. The Director of Central Drugs Laboratory (CDL), Kolkatta.
iv. The Director of Central Research Institute (CRL), Kasauli.
v. The Director of Indian Veterinary Research Institute (IVRI), Izatnagar.
vi. President of Pharmacy Council of India (PCI).
vii. President of Medical Council of India (MCI).
viii. The Director of Central Drug Research Institute (CDRL), Lucknow.

f) The Functions of Pharmacy Council of India (PCI) are as follows- **(Any three functions, each function 1 mark)**

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.

Que.3. Answer **any FOUR of the following: (each question carries 3 marks) 12 marks**

a) **Education Regulations: (3 marks)** Subject to the provision of section 10 of the Pharmacy Act, 1948, Central Council after approval of the Central Government may make regulations prescribing the minimum standard of education required for qualification as pharmacist called Education Regulations and prescribe:

1. Minimum qualification for admission to the course.
2. Nature and period of course of study.
3. Nature and period of practical training to be undertaken after completion of regular course (Not less than 500 hours covered in a minimum of 3 months in an institution, hospital, pharmacy or dispensary recognized by Central Council).
4. Subjects of examination and standards attained therein.
5. Equipment and facilities to be provided by institutions for students undergoing approved course of study.
6. Conditions to be fulfilled by institutions giving practical training.
7. Conditions to be fulfilled by authorities holding approved examinations.

b) Particulars on the label of ophthalmic suspensions – (3 marks)

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

2- Name and concentration of the 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.

c) **Ex-Officio members of DTAB (3 marks):**

i) The Director-General of Health Services, who is the chairman of the Board.

ii) The Drug Controller of India

iii) The Director of the Central Drug Laboratory, Calcutta

iv) The Director of the Central Research Institute, Kasauli

v) The Director of the Central Drug Research Institute, Lucknow.

vi) The Director of the Indian Veterinary Research Institute, Izatnagar

vii) The President, Pharmacy Council of India

viii) The President, Medical Council of India

d) Opium derivatives: (3 marks) It includes:

(i) Medicinal opium

(ii) Prepared opium

(iii) Phenanthrene alkaloids such as morphine, codeine, thebaine and their salts

(iv) Diacetyl morphine (heroin) and its salts

(v) All preparations containing more than 0.2% of morphine or any amount of diacetyl morphine.

e) Pharmacist in relation to physician: (3 marks)

1. A pharmacist, under no circumstances, should practice medicine, i.e. diagnosing diseases and prescribing medicines. However, in case of accidents or emergencies, he may render first aid services.

2. A pharmacist should not recommend any particular medical practitioner unless specially asked for.

3. Pharmacist should never enter into any secret agreement with medical profession to offer them commission or gifts by recommending his drug store. Pharmacist should not have any clandestine or underhand arrangement with any physician.

4. Pharmacist is a link between medical profession and public. He may be able to educate the public to maintain their health.

5. Pharmacists should neither discuss physicians' prescriptions with customers nor disclose to them the composition of prescriptions.

f) Penalty for: i) **Sale of substandard drugs – (1 ½ marks)**

1. Any adulterated drug or spurious drug or not of standard quality when used by a person is likely to cause his death or cause grievous hurt within the meaning of sec 320 of the I.P.C. shall be punishable with imprisonment for a term not less than ten years on first conviction which may extend to life imprisonment and with fine not less than ten lakhs or three times value of the drugs confiscated, whichever is more.

2. Any drug deemed to be adulterated but which is not likely to cause death or grievous hurt or any drug without valid licence shall be punishable with imprisonment three to five years and with fine not less than 1 lakh on first conviction and imprisonment not less than seven years but which may extend to ten years and with fine not less than 2lakh on any subsequent conviction or three times value of the drugs confiscated, whichever is more

3. Any drug deemed to be spurious but which is not likely to cause death or any grievous hurt shall be punishable with imprisonment not less than seven years but which may extend to imprisionment for life and with fine not less than 3 lakh on first conviction and with imprisonment not less than ten years which may extend to imprisionment for life with fine not less than 3 lakh on subsequent conviction. or three times value of the drugs confiscated, whichever is more

ii) **Use of Govt Analyst report for advertising as per D and C Act –(1 ½ mark)**
Whoever uses any report of a test or analysis made by CDL or govt analyst or extract from such report for the purpose of advertising any drug or cosmetic shall be punishable with fine up to Rs. 5000 on first conviction &whoever having been convicted of an offence under the sec.29 is again convicted of an offence shall be punishable with imprisonment up to 2 years or with fine not less than ten thousand or both

Que.4. Answer any FOUR of the following: (each question carries 3 marks) 12 marks

a) Licences issued for manufacture of drugs as per D & C Act:
(list 1 mark, explanation of any one 2 marks)

(A)Licence for manufacture of Schedule C and C1 drugs

(B) Licence for manufacture of Schedule X drugs

(C)Licence for manufacture of drugs other than those specified in Schedule C and C1 and Schedule X

(D)Licence for manufacture of drugs meant for examination, test or analysis

(E) Loan Licence

(F) Repacking Licence

(A) Manufacture of Schedule C and C1 drugs: A license may be obtained from the licensing authority on application and payment of prescribed fee. After inspection, the licensing authority if satisfied may issue the licence. A person, licensed to manufacture Schedule C and C1 drugs is required to observe the following conditions:

1. The licensed premise must conform to the requirements of GMPs specified in Schedule M and the licensee must provide adequate space, plant and equipment for manufacture of drugs.
2. The licensee must provide adequate arrangements for testing the strength and quality of drugs in the licensed premises and the testing unit should be separate from the manufacturing unit with an independent head.
3. The manufacture of drugs must be carried out by or under the active direction and personal supervision of technical staff (graduate in pharmacy or pharmaceutical chemistry with at least 18 months experience in manufacture of drugs OR a graduate in medicine with at least 3 years experience Or graduate in science with chemistry or microbiology OR graduate in chemical engg with at least 3 years experience.

4. The licensee should have adequate facilities for storage of drugs.
5. Records of details relating to manufacture and testing of drugs of each batch of drugs should be maintained.
6. The licensee must allow an inspector appointed under the Act to inspect the premises, processes of manufacture and testing of drugs, records required to be maintained and to take samples of any drug manufactured.
7. The licensee must report to the licensing authority any changes in the expert staff employed and also material changes in the plant or premise used for manufacture.
8. The licensee should on request furnish to the licensing authority samples of drugs for examination and if required full details of tests applied.

(B) Manufacture of drugs specified in Schedule X drugs: A license may be obtained from the licensing authority on application and payment of prescribed fee. After inspection, the licensing authority if satisfied may issue the licence. Conditions to be satisfied are –

1. Accounts of all transactions relating to the manufacture should be maintained in a serially bound and paged register as follows:
   a) Accounts of drugs used in the manufacture under the following headings:
   i) Name of the drug
   ii) Opening and closing balance on the day of manufacture specifying the quantity used.
   iii) Signature of the person in charge.
   b) Accounts of production under the following headings:
   i) Name of the drug and batch number
   ii) Date of manufacture
   iii) Quantity of raw material used in the manufacture
   iv) Anticipated and actual yields together with wastage
   v) Quantity of manufactured goods transferred.
   c) Accounts of manufactured drugs as below:
   i) Date of manufacture

ii) Name of drug and batch number
iii) Opening balance, quantity manufactured, quantity sold and closing balance
iv) Name and address of purchaser
v) Signature of person in charge

2. Drugs should be stored in bulk and if needed for manufacture outside storage place they should be kept in a separate place in the custody of a responsible person.
3. The licensee must submit a statement to the licensing authority every 3 months giving details of the state of manufacture of drugs and their supply and sale to other manufacturers, wholesale dealers, retailers, etc.
4. No Schedule X drug should be supplied by way of physician's samples.

(C) Manufacture of drugs other than those specified in Schedule C and C1 and Schedule X: A license may be obtained from the licensing authority on application and payment of prescribed fee. Following conditions must be satisfied for grant of licence:

1. The premise must conform to the requirements of GMPs specified in Schedule M and the licensee must provide adequate space, plant and equipment for manufacture of drugs.
2. The manufacture must be carried out under the active direction and personal supervision of competent technical staff (graduate in pharmacy or pharmaceutical chemistry with at least 18 months experience in manufacture of drugs OR graduate in science with chemistry or medicine OR chemical engg OR chemical technology with at least 3 years experience Or hold any foreign qualifications whose quality and content of training are comparable to the qualifications stated above.
3. The licensee should have adequate facilities for storage of drugs.
4. The licensee should keep records of the accounts of raw materials, production, manufactured drugs and analysis of drugs at least for a period of 5 years from the date of manufacture or analysis.

5. The licensee must allow an inspector appointed under the Act to inspect the premises, processes of manufacture and testing of drugs, records required to be maintained and to take samples of any drug manufactured.
6. The licensee must report to the licensing authority any changes in the expert staff employed and also material changes in the plant or premise used for manufacture.
7. The licensee should on request furnish to the licensing authority samples of drugs for examination and if required full details of tests applied.

(D) Manufacture of drugs for examination, test or analysis: The licence may be obtained from the licensing authority on application signed by the Head of the institution or Director of the firm or company which desires to undertake the manufacture. The drugs manufactured for the above purpose for should be kept in containers bearing the labels which indicate the purpose for which the drug has been manufactured. Following conditions must be observed:

1. The drugs should be used exclusively for the purpose for which they are manufactured.
2. Licensee must keep a record of the names and quantities of drugs manufactured and of the names of persons to whom they have been supplied.
3. The licensee must allow an Inspector appointed under the Act to inspect the licensed premises and satisfy himself that only examination, analysis or test work in being done.
4. The licensee must comply with such additional requirements of which he has been given at least one month's notice by the licensing authority.

(E**) Loan Licence -** It may be issued to a person who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee.

- Loan licenses are issued for the manufacture for sale or distribution of drugs other than those specified in schedule C, C_1 & X.

- Application for the grant or renewal of such license shall be made in Form 24-A & the license shall be issued in Form 25-A
- Application for grant or renewal of loan license to manufacture for sale of drugs specified in schedule C & C1 shall be made in Form 27A & the license shall be issued in Form 28-A & renewal certificate is issued in Form 26A

(F) Repacking licenses

Granted for the purpose of breaking up any drug from a bulk container into small packages & the labeling of each packages with a view to its sale & distribution.

License required for the repacking of drugs other than those specified in schedule C and C_1 & X

Applicant has to apply to the licensing authority in a prescribed form along with prescribed fees.

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

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

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

b) Offences and penalties as per Pharmacy Act, 1948: (any 3 offences, 3 marks)

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.

c) Operations controlled by State Govt. under NDPS Act, 1985: (3 marks)

i. Provide that the State Government shall fix from time to time the limits within which licences may be given for any cultivation of cannabis plant..

ii. Make provision that only the cultivators licensed by the prescribed authority of the State Government shall be authorized to engage in cultivation of any cannabis plant.

iii) Require that all cannabis, the produce of the land cultivated with cannabis plant, shall be delivered by the cultivators to the officers of the State Government authorized on this behalf.

iv) Empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered.

v)Prescribe the forms and conditions of licences or permits licences or permits for some or all of the following: possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption and use of poppy straw, opium, cannabis (excluding charas).

d) **Objectives and scope of pharmaceutical legislation:**

Objectives- (any 2 points, 1 mark)

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 4 points, 2marks)

1) It is related with legal system which regulate 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 gets 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.

e) **Define**:

i) **Bulk drug as per DPCO - (1 mark)** 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.

ii) **Formulation (2 marks)** – It means a medicine processes 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 or 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 medicine)

(b) Any medicine included in the Homeopathic system of medicine and

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

f) **Preparation of First Register under Pharmacy Act, 1940: (6 points, 3 marks)**

i) State Government by notification in Official Gazette constitutes a Registration Tribunal consisting of three persons and also appoints a Registrar who acts as the secretary of Registration Tribunal.

ii) The State Government then by notification ,specify a date on or before which application for registration accompanied with prescribed fee ,is made to Registration Tribunal.

iii) The Registration Tribunal examines every application received on or before the specified date and if satisfied that the applicant is qualified for registration directs the entry of the name of the applicant on the register.

iv) The first register so prepared is then published in a manner directed by State Government. Any person aggrieved by the decision of the Registration Tribunal expressed or implied in the published register may appeal within 60 days of publication to the authority appointed by State Government in this behalf.

v) The Registrar amends the register accordingly with decision of authority mentioned above and thereupon issues to every person a certificate of registration in prescribed form whose name is entered in the register.

vi) After constitution of State Council, this register is to be given into its custody and Government directs to credit application fee collected to State Council.

SUMMER– 14 EXAMINATION

Subject Code: **0814** **Model Answer** Page No: 23/31

Q.5 Answer any FOUR of the following: 12 marks

a) Differentiate between Bonded and Non-bonded laboratory (Three points) as per M.T.P. Act 1955. (each point 1 mark, any 3 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	Alcohol on which duty has not been paid shall be used under the excise supervision	Only the alcohol on which duty has already been paid shall be used
4	Preparations are deemed to be manufactured in bond when they are manufactured in premises licensed for this purpose.	Preparations are deemed to be manufactured outside bond when they are manufactured in premises licensed for this purpose
5	Bonded laboratory to function under excise staff.	No excise staff is required.
6	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.
7	Suitable for large scale manufacture.	Suitable for small scale manufacture.

b**) How retail price of drug is to be calculated under DPCO 1995.**

(Formula 1 mark & explanation 2 marks)

Ans. By applying the following formula, the retail price of the formulation is calculated:

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) State the objectives behind forming Medical Termination of Pregnancies Act, 1971 and define 'Guardian'.

Ans: Objectives:(2 marks)

This act was passed with the object

i)To provide for the termination of certain pregnancies by registered medical practitioners at approved places for bonafide medical reasons

ii) To provide strict & enhanced punishment for the violations of the provision of the Act.

iii) To remove provisions which were discriminatory to women (practice of ' female foeticide')

iv) and to provide the matters connected therewith.

Definition of "guardian"(1 mark)

means 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' {Sec. 2(a)}

d) Give offences and penalties under Drugs and Magic Remedies (O.A.) Act, 1954.

Ans : 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.

e) Define: (1 mark for each definition)

i) Drug Store:

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

ii) 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.

iii) 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.

f) Write procedure to be followed for disposal of drugs in the event of cancellation of drug licence as per D. and C. Act.

Ans: Procedure for disposal of drugs in the event of cancellation of license: (3 marks)

(1) In case a licensee, whose license has been cancelled, desires to dispose of the drugs he has in his possession in the premises in respect of which the license has been cancelled, he shall apply in writing to the licensing authority for this purpose, giving the following particulars, namely:—

(*a*) the name and address of the person to whom the drugs are proposed to be sold or supplied together with the number of the license for sale or manufacture, as the case may be, held by him,

(*b*) the names of drugs together with their quantities, batch numbers, the names and addresses of their manufacturers and the dates of their expiry, if any, proposed to be sold to the person mentioned in clause *(a).*

(2) The licensing authority may, after examination of the particulars referred to in sub-rule *(1)* and, if necessary, after inspection by an Inspector of the premises where the drugs are stocked, grant the necessary permission for their disposal.

SUMMER – 14 EXAMINATION

Que.**6. Answer any FOUR of the following: (each question carries 4 marks) 16marks**

a) Give form numbers of licence required for whole sale, retail sale, distribution and restricted licences for sale of drugs as per D. and C. Act.(1 mark each)

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	20	21	20-F
2. Restricted	20-A	21-A	-
3. Wholesale	20-B	21-B	20-G
4. Distribution from motor vehicle	20BB	21BB	-

b) Sate the classes of prohibited advertisements as per Drug and Magic Remedies (O.A.) Act, 1954 (4 marks, each class 1 mark)

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

c) Define : i) Illicit Traffic as under NDPS Act, 1985 (2 marks, any 4)

Ans: It includes:

1. Cultivating any coca plant or gathering any portion of coca plant;
2. Cultivating the opium poppy or any cannabis plant.
3. Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use of consumption interstate import, interstate export, import into India, export from India or trans-shipment of narcotic drugs or psychotropic substances.
4. Dealing in narcotic drugs and psychotropic substances.
5. Handling or letting any premises for use for any of the purposes referred in (i) to (iv).
6. Financing any activity by himself or through any other person in furtherance or in support of doing any of the aforesaid acts.
7. Harbouring persons engaged in any of the activities specified in (i) to (vi) or
8. Abetting or conspiring in the furtherance or in support of doing any of the aforesaid acts except to the extent permitted under the N.D. and P.S. Act, 1985, or any rule or order made, or any condition of any licence permit or authorization issued thereunder,

ii) Coca derivatives: (2 marks)

It includes:

1. Crude cocaine which can be used directly or indirectly for the manufacture of cocaine.
2. Ecgonine and all its derivatives from which it can be recovered.
3. Cocaine, which is methyl ester of benzoyl-ecogonine and its salts.
4. Preparations containing more than 0.1 % of cocaine.

d) Write a note on Drugs and Price Equalisation Account (DPEA) as per DPCO 1995. (4 marks)

Ans: Drug Prices Equalization Account (DPEA).

The Government may recover the dues accrued under the provision of the DPCO, 1979 from the manufacturer, importer or distributor as the case may be and deposit the same into an account known as Drug Prices Equalization Account.

The amount from DPEA shall be utilised for:

i. Paying the short fall between the retention price and common selling price or pooled price as the case may be to the manufacturer, importer or distributor, to increase the production or to secure the equitable distribution and availability at fair prices, of drugs.
ii. Meeting the expenses incurred by the Government in discharging the functions under this provisions.
iii. Promoting higher Education and Research in Pharmaceutical Sciences and Technology.

e) Define bonded manufactory. Give the requirements of bonded laboratory (any six).

Definition of bonded manufactory (1 mark) : 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.

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.

f) Mention whether termination of pregnancies at residence of RMP will be legal or illegal. State the places where it will be legal with facilities as per M.T.P. Act, 1971.

Ans. Termination of pregnancies at residence of RMP is illegal. **(½ marks)**

Approved places for termination of pregnancy: (1½ **marks)**

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.)

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