MODEL ANSWER

WINTER– 17 EXAMINATION

Subject Title: Pharmaceutical Jurisprudence Subject Code: 0814

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 anyequivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.

Q. No	Sub Q. N.	Answer	Marking Scheme
1		**Answer any Eight of the followings:**	**16M**
1	**a)**	**Give the objectives of the Medical Termination of Pregnancy Act, 1971.** The Medical Termination of Pregnancy Act, 1971 was passed by the parliament to provide for the termination of certain pregnancies by Registered Medical Practioner (RMP) at approved place for bonafied medical reasons.	**2M**
1	**b)**	**Give penalties for falsely claiming to be a registered under the Pharmacy Act, 1948.** 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- **Penalty:-** i) punishable with fine upto 500/- rupees on first conviction, and ii) with imprisonment upto six months or with fine upto 1000/- rupees or both on any subsequent conviction.	**2M**
1	**c)**	**Give the functions of Drugs 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.	**2M**
1	**d)**	**Define 'Advertisement' under the DMR (O.A.) Act, 1954.** 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	**2M**

1	**e)**	**State the objectives of the Drug Price Control Order, 1995.** i) To achieve adequate production. ii) To secure or regulate the equitable distribution. iii) To maintain and increase the supplies of bulk drugs and formulations and iv) To make these available at fair prices.	**2M (Each point ½ mark)**
1	**f)**	**Define 'Poppy straw' under the N.DP.S. Act, 1985.** **Poppy Straw:-** it includes all the parts (except the seeds) of the opium poppy after harvesting whether in original form or cut, crushed or powdered and whether or not juice has been extracted therefrom.	**2M**
1	**g)**	**State the importance of the 'Pharmacist' in health care system.** i) All the pharmacists working in different fields of profession are directly or indirectly related to nation's health. ii) Community pharmacist and hospital pharmacists are health professionals for the safe & effective use of drugs. iii) Pharmacy occupies an important position in the health care system. So the pharmacist should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product. Pharmacist is an expert on drugs. iv) With the developing trend in science and technology as well as in the potent and synthetic drugs, pharmacists' responsibility is increased to give information to the physician and the patients regarding the use, side-effects, etc. of such drugs in the interest of public health. v) Pharmacist is legally held responsible for the quality of product which is manufactures and distributed. They supply medicines against prescriptions. vi) They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes. vii)They provide link between Physician & Patient	**2M (any 4 points)**

viii)They are able to advice patients with minor illness

The profession of Pharmacy presently consists of -

i) Industrial pharmacist

ii) Hospital pharmacist

iii) Academic pharmacist

iv) Community pharmacist

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

1) Prescription adherence.
2) Storage and distribution of drugs.
3) Consultation and management.
4) Drug choice.
5) Drug monitoring.
6) Information and education.
7) Clinical pharmacokinetics.
8) Research and development and many other health activities.

1 h) Differentiate between 'drug store' and 'pharmacy'. **2M**

Sr. No	Drug store	Pharmacy
1	Licensed premises for the sale of drugs, which do not require the services of a qualified person.	Licensed premises for the sale of drugs which require the services of a "Qualified Person" and where the drugs are compounded against the prescriptions

1 i) State the objectives of the Drugs & Magic Remedies (O.A.) Act, 1954. **2M**

The drug and magic remedies act passed with following main objects

i) To control certain types of advertisement related to drug. e.g drug used in treatment of AIDS, Glaucoma, diabetes, epilepsy etc.

ii) To prohibit certain kinds of advertisement related to magic remedies which falsely claim and mislead the public.

iii) To provide for matter related to therewith.

<table>
<tr><td>1</td><td>j)</td><td>What do the schedules ‘F’ and ‘G’ to the D& C Rules, 1945 prescribe?

Schedule F: - Provisions applicable to Blood Bank requirements and licencing to process Blood Components.

Schedule G: - List of substances required to be taken only under supervision of a Registered Medical Practitioner.

OR

It is dangerous to take this preparation except under medical supervision.</td><td>1M for each</td></tr>
<tr><td>1</td><td>k)</td><td>Differentiate between ‘law’ & ‘ethics’.(any four points)
<table>
<tr><th>Sr. No</th><th>Law</th><th>Ethics</th></tr>
<tr><td>1</td><td>Definition- Rules of human conduct binding on all persons in a state.</td><td>Definition- Rules by which a profession regulates action & sets standards for all its members.</td></tr>
<tr><td>2</td><td>Law may prevent one from causing injury to another but it cannot force him to help his neighbour in hours of need.</td><td>Helping the neighbour is the function of ethics.</td></tr>
<tr><td>3</td><td>A law is something you must obey</td><td>Ethics is how society expects you to behave.</td></tr>
<tr><td>4</td><td>Law deals with actions that are punishable.</td><td>Ethics deals with right & wrong.</td></tr>
<tr><td>5</td><td>Laws are written & approved documents.</td><td>Ethics are also written words but they are not carrying legal status</td></tr>
<tr><td>6</td><td>If law is broken, a violator may be subjected to punishment, a fine or imprisonment.</td><td>If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges</td></tr>
</table></td><td>2M (1/2 Mark for each)</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table>

1	**l)**	**What punishment is prescribed for contravention of provisions in relation to cannabis plant & cannabis under the NDPS Act, 1985?** **Punishment for contravention in relation to cannabis plant and cannabis**.-Whoever, in contravention of any provisions of this Act or any rule or order made or condition of license granted there under, **(a)** cultivates any cannabis plant; or **(b)** produces, manufactures, possesses, sells, purchases, transports, imports inter- State, exports inter-State or uses cannabis, shall be punishable [(i) where such contravention relates to **clause (a)** with rigorous imprisonment for a term which may extend to ten years and shall also be liable to fine which may extend to one lakh rupees; and (ii) where such contravention relates to **sub-clause (b),-** (a) and involves small quantity, with rigorous imprisonment for a term which may extend to, one year or with fine, which may extend to ten thousand rupees, or with both; (b) and involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years, and with fine which may extend to one lakh rupees. (c) and 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 but which may extend to two lakh rupees: Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.]	**2M** **(1Mark for each clause)**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**What are the functions of the Central council under the Pharmacy Act, 1948?** 1. To prescribe the minimum standards of education required for qualification as a pharmacist (This can be provided by making the rules as education regulations, which prescribes minimum qualification for admission, duration of the course, details of the syllabus, practical training and examination, minimum facilities required for conduct of	**3M**

		course, examination & practical training). 2) To regulate the minimum educational standard. (For this purpose, Council appoints Inspectors to inspect institutions, providing the minimum standards in education in pharmacy and report on the facilities available and decides whether the institute should be recognised or not. 3) To recognise qualifications granted outside territories to which Pharmacy Act 1948 extends for the purpose of qualifying for registration under the said Act. 4) To compile and maintain a central register for pharmacist containing names of all persons for the time being entered in the state register. 5) The Council has to furnish copies of its minutes and those of executive committee, together with the summary of annual activities and accounts to the central Government. 6) Any other function that may be assigned to the Central Council in the furtherance of the objectives of the Pharmacy Act, 1948.	
2	**b)**	**State the rules prescribed by state Government in relation to possession for the sale and sale of any poison.(any six)** 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. Safe custody of poisons and labelling 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.	**3M (½ Mark for each)**
2	**c)**	**Give the procedure followed for the movements of the goods from one warehouse to another.** 1. **Bond for due arrival and re-warehousing :-** When goods are removed from one warehouse to another. The consigner has to enter in bond with Excise Commissioner.	**3M**

		For security purpose at least twice amount of duty payable than goods. Such bond should remain valid until officer in-charge received certificate for goods have been re-warehoused. 2. **Remover may enter into general bond :-** EC will permit any person for removing goods from one warehouse to another, by entering into general bond with sufficient security as prescribed by EC 3. **Procedure for removing goods:-** For removal of goods the consigner has to apply in triplicate with sufficient documents to the officer in-charge at least 24hrs advanced. Officer may take account (confirmation) of goods and allow them to be remove good by completing removal certificate on all copies of application. Send duplicate copy to officer in-charge of destination warehouse and also give transport permit and triplicate copy of application to consigner. On arrival of goods at the destination warehouse, the consigner has to present triplicate copy of application along with transport permit to officer in-charge. Officer may take account (confirmation) of goods and then complete the re-warehousing certificate and issue to consignee with triplicate copy. The consigner shall present both triplicate copy and re-warehousing certificate to officer in-charge of initial warehouse within 90days of issue of transport permit. If consigner fails to present these documents to the officer in-charge, he shall pay the duty within 10 days of demand. If duty is not paid, he shall not permit to make fresh approval for removing goods Goods may be kept in warehouse for maximum 3yrs from date of their deposit or for such extended period as may have been permitted by excise commissioner.	
2	**d)**	**State the qualifications for appointment of 'Drug Inspector' as per the D&C Act, 1940.** A person who is appointed an Inspector should possess the following qualifications 1) Graduate in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized University.	**3M**

		Provided that for the purpose of inspection of manufacture of substances specified in Schedule C, a person appointed as a Drug Inspector should have - i) Not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C, or ii) Not less than 18 months experience in testing of at least one of the substances in Schedule C in approved Laboratory, or iii) Not less than three year experience in the inspection of firms manufacturing any of the substances specified in Schedule C during the course of their services as Drugs Inspector. Provided further that the first 4 years from the date on which Chapter IV of the Act takes effect in the States, person whose qualification, training & experience are considered adequate may be appointed as Inspector & their appointments continued even after 4 years, if the State Govt. is satisfied.	
2	**e)**	**Define 'Addict' and 'Cannabis' under NDPS Act, 1985.** **Addict**: A person habitual to regular use of any narcotic drug or psychotropic substance is known as addict. **Cannabis:** It includes the following: (i) Charas, which is a resin in crude or purified form obtained from the cannabis plant which includes concentrated preparations and resin known as hashish oil or liquid hashish. (ii) Ganja, which comprises of flowering or fruiting tops of the cannabis plant (excluding seeds and leaves not accompanied by the tops) (iii) Any mixture with or without any neutral material of ganja or charas or any drink prepared from them	**1M Addict, 2M cannabis**
2	**f)**	**How do Schedule 'X' drugs are supplied on retail counter?** Sale of schedule X drugs:- 1. Schedule X drugs shall be supplied only on a prescription of a RMP and such prescription should be in duplicate, one copy of which is retained by licensee and preserved for at least 2 years. Unless otherwise stated in the prescription by the	**3M**

		prescriber, such drugs must not be dispensed more than once. 2. The supply of drugs specified in schedule X shall be recorded at the time of supply in a bound and serially page numbered register, specially maintained for the purpose and separate pages shall be allotted for each drug and the following particulars shall be entered in the register. i) Date of supply and opening and closing stocks of drug on that day and relevant bill numbers. ii) Name of drug, its manufacturer's name and Batch number or lot number. iii) Name and address of the purchaser/patient. iv) Date of prescription and name and address of RMP v) Signature of the registered pharmacist under whose supervision supply is made. vi) Specify the name and address of the patient or name and address or the owner of the animal if drug is for veterinary use. 3. Transaction of schedule X drug should be recorded in separate register in which in addition to the above details, the quantities purchased should be recorded together with name and address of supplier and his license number. 4. Record of supply of schedule X drugs to Registered Medical Practitioners, hospitals, infirmaries or other institutions, should be preserved at least for 3 years from the date of supply. 5. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and rules and thereunder. 6. 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.	
3		**Attempt any FOUR of the followings**	**12M**
3	**a)**	**Give the constitutions of Joint State Pharmacy Council under the Pharmacy Act, 1948.** <u>Joint State Pharmacy Council is constituted as follows</u>: 1) As provided in the agreement not less than 3 and not more than 5 members elected amongst the registered pharmacists of each participating state. 2) As agreement provides, not less than 2 & not more than 4 members nominated by each	**3M**

		participating State Governments of whom more than half should possess degree or diploma in pharmacy or pharmaceutical chemistry or be a registered pharmacist. 3) One member elected by the members of each Medical Council from amongst themselves, of each participating state. The following are ex-officio members: 1) Chief administrative medical officer of each participating State. 2) Officer in-charge of the Drug Control Organization of each participating State under D&C Act, 1940. 3) Government Analyst appointed under D&C Act, 1940 of each participating state	
3	**b)**	**How Bonded Laboratory be constructed?** **Construction of bonded laboratory**: 1) A Spirit store, (if a distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory). 2) Separate room or rooms for the manufacture of medicinal preparations and toilet preparations. 3) Separate room or 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) Every room should bear a board indicating the name of room and serial numbers 6) The pipes from sinks or wash-basins should be connected with general drainage of the laboratory. 7) The gas and electric connection supply should be such that their supply can be cut-off at the end of day's work. 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 bonded 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. No alterations in the bonded premises shall be made without the	**3M**

		previous orders of the Excise Commissioner. 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 & all the finished preparations on which duty has not been paid should bear excise ticket locks.	
3	**c)**	**Describe in detail Drugs Prices Equalisation Account (DPEA)** **Drugs price Equalisation Account (DPEA) –** The Government may by recover the dues accrued under the provisions of the Drugs (Prices Control) Order, 1979 from the manufacturer, importer or distributor as the case maybe & deposit the same into an account known as Drugs Prices Equalization Account. The amount, from Drugs Prices Equalisation Account shall be utilized for : (i) Paying the shortfall between the retention price and the common selling price or the pooled price as the case may be to the manufacturer or importer or distributor, to increases the production, or to securing the equitable distribution and availability at fair prices, of drugs. (ii) Meeting the expenses incurred by the Government in discharging the functions under this provision & (iii) Promoting higher education and research in Pharmaceutical Sciences and Technology.	**3M**
3	**d)**	**What are the powers of Central Govt. to prohibit & regulate the operations involved under the N.D.P.S. Act, 1985.** Operations prohibit & regulated by Central government under N.D.P.S. Act, 1985 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 possession, transport, import inter-State, export inter-State, warehousing, sale, purchase, consumption & use of poppy straw. v) The sale of opium & opium derivatives from the Central Government factories for	**3M (Each points ½ marks, Any 6)**

		export from India or sale to State Government or to manufacturing chemists. vi) 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. vii)The manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption & use of essential narcotic drugs viii) The manufacture, possession, transport, sale, purchase, import inter-state, export inter-state, use or consumption of psychotropic substances ix)The import into India & export from India & transshipment of narcotic drugs & psychotropic substances.	
3	**e)**	**Give the particulars that should appear on label of 'Ophthalmic preparations'** **(a) Ophthalmic solutions & suspensions** – i) The statement, 'Use the solution within a month after opening the container' ii) Name and concentration of preservative used. iii) The words 'NOT FOR INJECTION'. iv) Special instructions regarding storage, wherever applicable. v) A cautionary legend reading as: **Warning** : i) If irritation persists or increases, discontinue the use and consult physician. ii) Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solution. **(b) Ophthalmic ointments** i) Special instructions regarding storage wherever applicable. ii) Warning: If irritation persists or increases, discontinue the use and consult physician.	**3M**
3	**f)**	**Explain the ethics for pharmacist in relation to his profession.** **Role of pharmacist in relation to his profession** 1) A pharmacist should observe the law and ethical principles to maintain the standard of the profession. 2) A pharmacist should extend the help and co-operation to his fellow pharmacist in an	**3M**

		emergency and legitimate needs. 3) A pharmacist should try to weed out the undesirable corrupt or dishonest conduct of the member of his profession maintaining its status in society. 4) A pharmacist should have a fair knowledge of laws of the state and nation pertaining to food, drug, pharmacy education, health etc. 5) A pharmacist should have an upto date knowledge of professional matters. It should associate himself with various pharmaceutical organizations, the aims and objects of which are compatible with this code of ethics. 6) A pharmacist should not perform such acts which will bring discredit to his profession or to himself.	
4		**Attempt any FOUR of the followings**	**12M**
4	**a)**	**Describe offences & penalties under the Drugs and Magic Remedies (O.A.) Act,1954** **Offence-** 1) Contravention of any of the provision of this Act or rules thereunder: **Penalties**: a) Imprisonment 6 month or with fine or with both on 1st conviction. b) Imprisonment 1 year or with fine or with both on subsequent conviction. **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.	**3M** **($1^{1/2}$mark for each offence & penalty)**
4	**b)**	**Define: (i) Net worth; and(ii) Free reserve, as per DPCO,1995** **(i) Net worth:** 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 the operational activity**.** **(ii) Free reserve**: It 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.	**3M** **($1^{1/2}$mark for each def.)**

4	**c)**	**What "Education Regulations" are as prescribed under the Pharmacy Act, 1948?** Subject to the provision of section 10 of Pharmacy Act, 1948, Central Council after approval of Central Government may make regulations prescribing the minimum standard of education required for qualification as a pharmacist is called Education Regulations 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. Central Council before submitting the ER or any amendment thereof, as the case may be to the Central Government for approval, sends copies of draft of ER to all State Governments. Then ER is published in official Gazette by Central Government.	**Definitio n 1M, Explanat ion 2 M**
4	**d)**	**Give bonafied reasons for termination of pregnancy under M.T.P.,1971.(any six)** **1)** 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. **2)** In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian. **3)** 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	**3M (½ mark for each)**

		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. **4)** 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. **5)** 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. **6)** 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.	
4	**e)**	**State in brief powers of Drugs Inspector under D&C Act, 1940 and rules thereunder.** 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 manufactured 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 **vi) Give order** in writing to the person in possession of drug or cosmetic in respect of	**3M (½ mark for each, Any 6)**

		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.	
4	**f)**	**Give functions of Central Drugs Laboratory.** **Functions of Central Drug Laboratory (CDL)** **1)** To analyse or test the samples of drugs or cosmetics sent to it by Custom collectors or any other authorized officers or courts **2)** To carry out such other duties as may be entrusted to it by Central or State Govt. after consultation with the DTAB **3)** In case of the following drugs or classes of drugs, function of CDL carried out at the Central Research Institute, Kasauli, and such functions are exercised by the Director of the said Institute:- Sera, Solution of serum proteins intended for injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature and sterilized surgical suture & Bacteriophages. **4)** The functions regarding Oral Polio Vaccine are exercised by the Deputy Director & Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute Kasauli. **5)** In case of the following drugs or classes of drugs shall be carried out at the Indian Veterinary Research Institute, Izatnagar or Mukteshwar. Such functions are exercised by the Director of either of the said institutes: Anti-sera, Vaccines, (Toxoids, Diagnostic Antigens for veterinary use. **6)** In case of condoms the functions of CDL are carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad, and such functions are exercised by the Director of the said Laboratory.	**3M** **(½ mark for each, Any 6)**

		7) In case of **VDRL Antigen (Veneral Disease Ref. Lab.)** the functions of CDL are carried out at Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions are exercised by Director of Serologist and Chemical Examiner of the said Laboratory. **8)** In respect of Intrauterine Devices and Felope Rings, the functions of laboratory shall be carried out at the Central Drug Testing Laboratory, Thane, Maharashtra and such functions shall be exercised by the Director of the said Laboratory. **9**) In respect of human blood and human blood products including components, to test for freedom of HIV antibodies, shall be carried out by the following Institutes, Hospitals and such functions are exercised by the head of the respective Institutes- a) National Institutes of Communicable Disease, Department of Microbiology, Delhi. b) National Institute of Virology, Pune c) Centre of Advanced Research in Virology, Christian Medical College, Vellore.] **10)** In respect of Homoeopathic medicines the function of CDL carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said laboratory **11)** In respect of Blood Grouping reagent and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus the function of CDL carried out at the National Institute of Biologicals, NOIDA and such functions are exercised by the Director of the said laboratory.	
5		**Attempt any FOUR of the followings**	**12M**
5	**a)**	**Give the classes of advertisement which are prohibited under Drug and Magic Remedies (OA) Act, 1954?** 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	**3M** **(1M for each, any 3)**

		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	
5	**b)**	**Describe the offences & penalties under poison act 1919.** **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.	**Offences** **$1^{1/2}$M** **Penalties** **$1^{1/2}$ M**

5	**c)**	**Give the formula for calculation of retail price of formulations and explain the terms as per DPCO, 1995.** 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.	**3M (1M – formula, 2M- explanation)**
5	**d)**	**Define (i) Registered Pharmacist and (ii) Repatriate under Pharmacy Act, 1948-** **i) 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. **ii) Repatriate :** Any person of a Indian origin who on account of civil disturbances in any area now forming, part of Burma, Sri Lanka or Uganda, or any other country has after the 14th day of April 1957, left or has been displaced from his place of residence in such area & who has since then been residing in India	**3M ($1^{1/2}$mark for each def.)**

5	**e)**	**State the penalty for following offences:** **(i)** Sale of dutiable good except in prescribed containers bearing a label. Penalty- Fine upto 1000/- & confiscation of the goods related with this offence. **(ii)** Keeping of stocks of dutiable goods in disorderly manner (not in accordance with the provision of this Act.) Penalty- Fine upto Rs. 1000/- **(iii)** Vexations search, seizure by any officer exercising powers under this Act or rules there Under the M.T.P.(E.D.) Act,1955 Penalty- Fine upto Rs. 2000/-	**3M** **(1M for each penalty)**
5	**f)**	**What do you mean by** **(i)Restricted licences-** **(ii) Loan licenses** **(i)Restricted licences :** (i)Restricted licences shall be issued subject to the discretion of the Licensing Authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person. (ii)Licences to itinerant vendors shall be issued only in exceptional circumstances for bonafide traveling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in rural areas where other channels of distribution of drugs are not available. (iii)For restricted licence, applicant has to make an application in Form-19A and the licence issued for drugs other than those specified in schedule C,C(1),and X in Form 20A and for drugs specified in schedule C, C(1) in Form 21-A (iii)The restricted licence in Form 21-A may also issued to a travelling agent of a firm for drugs specified in Schedule C. (iv)Such licence is not needed for venders for the specific purpose of distribution to medical practioner or dealers. (v)Such licence in not needed to traveling agents of licensed manufacturers, agents of such manufacturers and importers of drugs engaged in free distribution of samples of	**3M** **($1^{1/2}$mark for each)**

		medicine among members of the medical profession, hospitals, dispensaries and the medical or research institutions. **(ii) Loan licence:** It means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee/ manufacturer. (i)Application for the grant or renewal of loan licences to manufacture for sale or for distribution of drugs other than those specified in Schedule C, Schedule C (1) & Sch. X shall be made up to ten items for each category of drugs shall be made in Form 24-A accompanied by a licence fee of rupees 6000/- & an inspection fee of rupees 1500/- to the licensing authority. (ii)The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, & facilities for testing, to undertake the manufacture on the behalf of the applicant for a loan licence (iii)Application for manufacture of more than ten items for each category of drug on a loan licence shall be accompanied by an addition fee of rupees 300/- per additional item specified in Schedule M.& M-III (iv)If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless he may, on payment of a 1000/- Rs issue a duplicate licence. (v)An original licence or a renewed licence in Form 25 valid for a period of five years on which it is granted or renewed.	
6		**Attempt any FOUR of the followings**	**16M**
6	**a)**	**What are the powers of State Government to prohibit, regulate and control the operations involved under N.D.P.S. Act,1985** **<u>Prohibit, regulated operations by State Government</u>** State Government may by rules prohibit and regulate : 1) The possession, transport, inter-state import, inter-state export, sale, purchase,	**4M** **(2M- prohibit, regulate, 2M-**

		warehousing, consumption & use of poppy straw. 2) The possession, purchase, sale, transport, inter-state import, inter-state export, consumption & use of opium. 3) Cultivation of any cannabis plant, manufacture, production, possession, purchase, sale, transport, inter-state import, inter-state export, consumption or use of cannabis. 4) Manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess; 5) Possession, purchase, sale, transport, inter-state import, inter-state export, use or consumption of manufactured drug other than prepared opium and of coca leaf and any preparation containing any manufactured drug. 6) Manufacture & possession of prepared opium from opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption. **Controlled operations by State Government** 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). vi) Empower the state government to declare any place to be warehouse wherein it shall	**control)**

		be the duty of the owners to deposit all such poppy straw as is legally imported inter-state and is intended for export inter-state or export from India; to regulate the safe custody of such poppy straw warehoused and the removal of such poppy straw for sale.	
6	**b)**	**Explain the ethics for pharmacist in relation to his job.** **1. Pharmaceutical services:** i) A pharmacist should provide efficient and reasonably comprehensive pharmaceutical services through the medical store or pharmacy. 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) In every pharmacy/ drug store, there should be qualified pharmacist to have personal control the pharmacy. 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 the premises should reflect the professional character of pharmacy. **3. Prescriptions:** i) Prescriptions presented for dispensing 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 so that the patients will lose their faith in the physicians or prescribers after receiving the prescriptions. 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 any error in the prescription, it should be referred back to the prescriber for necessary correction or approval of the change suggested. v) If at all change in the prescription 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.	**4M**

		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 practical 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.	
6	**c)**	**What is the purpose of Pharmaceutical Legislation? Explain recommendations of D.E.C.(any six)** **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. **Recommendations of DEC.** 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. These councils would maintain the register containing the names & addresses of the registered pharmacists. ii) Creation of Drug Control Departments 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.	**4M (1M-purpose,** **Each recommendation ½ M ,any six)**

6	**d)**	**Give the procedure for getting approval to the Institutions or Authorities providing courses of study & examination.** 1) **Applications by Institutions / Authority to the Central Council**: An Institution or Authority, which conducts course of study or holds an examination of the pharmacist, has to apply to the Central Council (PCI) for approval of the course or examination. **2) Inspection**: The Central Council, after receiving such applications, depute its inspectors to visit the institution and ascertain whether the institution has the prescribed facilities for imparting training or holding examination in accordance with ER or not. Inspectors may also attend any examination, to judge its standards without interfering with its conduct. The Inspectors then report to the Council on the sufficiency or otherwise of the facilities available in the institution and on the conduct and Standard of the examinations 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.	**Each Point 1 M**
6	**e)**	**Define "Adulterated Drug" as per the Drugs and Cosmetics Act 1940.** A drug shall 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 colour other than prescribed which may be used for the purpose of colouring only; or	**4 M**

		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.	
6	**f)**	**Give the constitution of Drugs Technical Advisory Board (DTAB)** **Ex-officio members.** i) The Director General of Health Services, who is the 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. **Nominated Members** -Following members nominated by Central Government. i) Two persons from among persons who are in-charge of the drugs control in the states ii) One person from the pharmaceutical industry. iii) Two Government Analysts. **Elected Members** i) One teacher in Pharmacy, Pharmaceutical Chemistry or Pharmacognosy on the staff of an university or affiliated college elected by the Executive Committee of Pharmacy Council of India. ii) One teacher in medicine or therapeutics on the staff of an university or affiliated college elected by the Executive Committee of Medical Council of India. iii) One Pharmacologist, elected by the Governing Body of the Indian Council of Medical Research. iv) One person elected by the Central Council of Indian Medical Association. v) One person elected by the Council of the Indian Pharmaceutical Association.	**Ex-officio $1^{1/2}$ M** **Nominated 1 M** **Elected $1^{1/2}$ M**