



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(2x8)
1	a)	Give two important recommendation of D. E. C. 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.	1M for each, any 2
	b)	What does schedule 'O' and schedule 'M' prescribed as per D & C Act 1940? Schedule O- Standards for disinfectant fluids. Schedule M - Good manufacturing practices & requirements of factory premises, Plant, equipment etc. for manufacture of drugs.	1M for each
	c)	Give schedule for following drugs: i) Phenformin- Schedule G ii) Analgin- Schedule H iii) Phenobarbitone- Schedule H, X iv) Tolbutamide- Schedule G	0.5 M for Each schedule
	d)	Define the term "Loan license" under D & C Act, 1940 and Rules. Loan license means a license 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.	2M



e)	<p>How will you differentiate between law and ethics? (Any two points)</p> <table border="1"> <thead> <tr> <th data-bbox="272 430 349 541">Sr. No.</th> <th data-bbox="349 430 846 541">Law</th> <th data-bbox="846 430 1382 541">Ethics</th> </tr> </thead> <tbody> <tr> <td data-bbox="272 541 349 709">1</td> <td data-bbox="349 541 846 709">Rules of human conduct binding on all persons in a state or nation.</td> <td data-bbox="846 541 1382 709">Rules by which a profession regulates action & sets standards for all its members.</td> </tr> <tr> <td data-bbox="272 709 349 926">2</td> <td data-bbox="349 709 846 926">Law may prevent one from causing injury to another but it cannot force him to help his neighbor in hours of need.</td> <td data-bbox="846 709 1382 926">Helping the neighbour is the function of ethics.</td> </tr> <tr> <td data-bbox="272 926 349 1037">3</td> <td data-bbox="349 926 846 1037">A law is something you must obey.</td> <td data-bbox="846 926 1382 1037">Ethics is how society expects you to behave.</td> </tr> <tr> <td data-bbox="272 1037 349 1148">4</td> <td data-bbox="349 1037 846 1148">Law deals with actions that are punishable.</td> <td data-bbox="846 1037 1382 1148">Ethics deals with right & wrong.</td> </tr> <tr> <td data-bbox="272 1148 349 1260">5</td> <td data-bbox="349 1148 846 1260">Laws are written & approved documents.</td> <td data-bbox="846 1148 1382 1260">Ethics are also written words but they are not carrying legal status.</td> </tr> <tr> <td data-bbox="272 1260 349 1493">6</td> <td data-bbox="349 1260 846 1493">If law is broken, a violator may be subjected to punishment, a fine or imprisonment.</td> <td data-bbox="846 1260 1382 1493">If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges.</td> </tr> </tbody> </table>	Sr. No.	Law	Ethics	1	Rules of human conduct binding on all persons in a state or nation.	Rules by which a profession regulates action & sets standards for all its members.	2	Law may prevent one from causing injury to another but it cannot force him to help his neighbor in hours of need.	Helping the neighbour is the function of ethics.	3	A law is something you must obey.	Ethics is how society expects you to behave.	4	Law deals with actions that are punishable.	Ethics deals with right & wrong.	5	Laws are written & approved documents.	Ethics are also written words but they are not carrying legal status.	6	If law is broken, a violator may be subjected to punishment, a fine or imprisonment.	If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges.	1M for each, any two
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f)	<p>Define "Poison". Give two examples of Poison under Poisons Act, 1919.</p> <p>Definition:- Any substance specified as a poison in a rule made or notification issued Under the Poison Act,1919 shall be deemed to be a poison for the purpose of this Act.</p> <p>Examples:-</p> <p>List A poisons: Aconite, Aconine, Arsenic, Atropine, Belladonna, Cantharides, Chloral hydrate, Coca, Corrosive Sublimate, Potassium cyanide, Diamorphine (Heroin), Diethyl barbituric Acid, Digitalis, Ecogonine, Ergot of Rye, Lead, Nux Vomica, Strychnine, Morphine, Pectrotoxine, Prussic acid, Savin and its oils, Stramonillan, Stropanthus,</p>	1 M Definition 1M Examples (any2)																					



	<p>Stropanthin Tartar emetic, Tetraethyl lead.</p> <p>List B poisons: Essential oils of Almonds (unless deprived of prussic Acid), Antimonial wines, all salts of Barium, except Barium sulphate, Tincture of Contharides, Carbolic acid, Chloroform, Mercuric Sulphocyanide, Oxalic acid, Poppies, All oxides of Mercury, Sulphonal, Zinc Chloride.</p>	
g)	<p>List the facilities provided for termination of pregnancy under MTP Act, 1971.</p> <p>Facilities :-</p> <p>Upto <u>12 weeks MTP</u> : Places may be approved with following facilities : {Rule-5(l) (ii)}</p> <ul style="list-style-type: none">• Gynaecology Examination Table/ Labour Table,• Resuscitation and Sterilisation equipment,• Drugs & Parental Fluids,• .Backup facilities for treatment of shock, &• Facilities for Transportation. <p>Upto <u>20 weeks MTP</u> : Places may be approved with following facilities : {Rule-5(l) (ii)a,b,c}</p> <ul style="list-style-type: none">• An operation table and• Instruments for performing abdominal or Gynecological surgery.• Anaesthetic Equipments, Resuscitation and Sterilisation equipment.• Drugs and parenteral fluids for emergency use, as notified by Government of India from time to time	2M
h)	<p>Define “Advertisement” as per Drugs & Magic Remedies Act, 1954.</p> <p>Advertisement: It includes</p> <p>i) Any notice, circular, label, wrapper or otherwise such document, and</p> <p>ii) Any announcement made orally or by means of producing or transmitting light, sound or smoke.</p>	2M
i)	<p>Define:</p> <p>i) Restricted preparation</p> <p>ii) Unrestricted preparation</p>	1M for each



		<p>as per medicinal and Toilet Preparation Act,1955.</p> <p>i) Restricted Preparation: These are medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages.</p> <p>ii) Unrestricted preparation: These are medicinal preparations which are considered to be not capable of being misused as ordinary alcoholic beverages.</p>	
	j)	<p>Define' Registered Pharmacist" as per the Pharmacy Act, 1948.</p> <p>Registered Pharmacist: means a person whose name for the time being is entered in the register of pharmacists of the state in which he is for the time being residing or carrying on his profession or business of pharmacy.</p>	2M
	k)	<p>State the object of Narcotic Drugs and Psychotropic Substance Act, 1985.</p> <p>The main object of this act is-</p> <p>i) To consolidate & amend law relating to Narcotic Drugs</p> <p>ii) To make strict provision to prohibit, control & regulate the operations relating to Narcotic Drugs & Psychotropic Substances.</p> <p>iii) To provide matter connected therewith.</p>	2M
	l)	<p>What do you mean by clandestine arrangement as per Code of Pharmaceutical Ethics?</p> <p>No pharmacist should enter into any secret arrangements or contract with a physician, to offer him any commission or any advantage by recommending his dispensary or drugstore.</p>	2M
2		<p>Answer any FOUR of the followings</p>	12M (3x4)
2	a)	<p>Discuss ethics for Pharmacist in relation to his trade</p> <p>A] Price Structure-</p> <p>Prices of drugs & medicinal preparations charged from the customers should be fair & including dispensing & compounding charges without unduly taxing the purchaser.</p> <p>B] Fair trade practice-</p> <p>A pharmacist should not make any attempt to capture the business of fellow pharmacist by unhealthy competition i.e. by offering reduced price, gifts, prizes etc.</p> <p>Trade mark, labels, symbols or any other signs of other pharmacist should not be copied</p>	3M



		<p>or imitated.</p> <p>Drugs or other ingredients required should always be purchased from reputable sources.</p> <p>C] Hawking of drugs & other-</p> <p>Hawking of drugs & medicines should not be practiced & any attempt should not be made to collect the orders from door to door.</p> <p>Self-servicing method in the pharmacy or drug stores should not be allowed as it would encourage self-medication which is undesirable & dangerous.</p> <p>D] Advertisement & display-</p> <p>There should not be any display or advertisement on the premises, in the newspaper or elsewhere regarding the abilities & services provided by the pharmacy.</p> <p>The pharmacist should not make such advertisements which contain:</p> <ul style="list-style-type: none">(i) Misleading or exaggerated statements,(ii) A guarantee of therapeutic efficiency,(iii) An offer to refund money paid(iv) An appeal to fear(v) The word 'cure' in reference to an ailments or symptoms of ill-health.	
2	b)	<p>What are Education Regulation and explain what they state?</p> <p>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</p> <p><u>Education Regulations may prescribe –</u></p> <ul style="list-style-type: none">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.	<p>1M definition</p> <p>2M Explanati on</p>



		<p>vi) Conditions to be fulfilled by institutions giving practical training.</p> <p>vii) Conditions to be fulfilled by authorities holding approved examinations.</p> <p>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.</p>	
2	c)	<p>Write about the offences and penalties of Pharmacy Act, 1948.</p> <p>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 up to five hundred rupees on first conviction, and with imprisonment upto six months or with fine up to 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.</p> <p>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.</p> <p>3) Failure to surrender certificate of registration: Is also punishable with fine upto fifty rupees.</p> <p>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</p>	<p>1M for Each, any three</p>
2	d)	<p>State the classes of Advertisements which are exempted from application of the provisions of Drug and Magic Remedies Act?</p> <p>Classes of exempted advertisements:</p> <p>1. Any advertisements relating to the drugs printed or published by the Government or</p>	<p>½ M for each, Any6</p>



		<p>any other person with prior permission of the Government.</p> <p>2. Any advertisement relating to a drug which is sent confidentially in the prescribed manner to registered medical practitioner.</p> <p>3. Advertisements including any book or treatise dealing with any matter relating to the diseases, disorders or conditions which are otherwise prohibited provided published from bonafide scientific or social point of view.</p> <p>4. Displayed signboards or notices by registered medical practitioners on his premises indicating that the treatment is undertaken for any disease, disorders or conditions specified in the schedule to this Act or in the rules made under this Act.</p> <p>5. Advertisements relating to the drugs which comply with the required conditions as follows:</p> <p>(a) Leaflets or literature along with packing of drugs; or advertisements of drugs in medicinal, pharmaceutical, scientific and technical journals</p> <p>(b) Therapeutic index or price list published by licensed manufacturer, importer or distributor of drugs or medical literature distributed by medical representatives.</p> <p>With conditions that:</p> <p>6. The advertisement should contain only the information required for the guidance of registered medical practitioner regarding:</p> <p>(a) therapeutic indications;</p> <p>(b) route of administration;</p> <p>(c) dosage and side effects of such drug or drugs; and</p> <p>(d) the precautions to be taken in treatment with the drug</p> <p>7. The distribution of such literature should be given to registered medical practitioner, dispensaries, hospitals, medical and research institutions, chemists and druggists or pharmacies</p>	
2	e)	<p>Write powers of drug inspector (any 6) as per D & C Act, 1940.</p> <p>Within the local limits for which the Inspector is appointed, he may:</p> <p>i) Inspect -</p> <p>Any premises wherein any drug or cosmetic is being manufactured. And also he may</p>	<p>½ M for each, Any6</p>



inspect the means employed for standardizing and testing the drug or cosmetic.
Any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed.

ii) Take samples of any drug or cosmetic-
Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed.
From any person, conveying, delivering or preparing to deliver any drug or cosmetic to a purchaser or a consignee.

iii) Search any person 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 an offence is being committed or has been committed.

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

vi) Give order in writing to the person in possession of the drug or cosmetic in respect of which the offence has been or is being committed, not to dispose of any 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, & 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 & 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 purposes of this act & the rules made thereunder.

If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter he shall be punishable with imprisonment which may extend to three years or with fine or with both.

2

f)

Give the functions of Central Drug Laboratory (any 3).

1 M for each,



- 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.
- 7) In case of **VDRL Antigen (Venereal 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-

Any 3



		<p>a) National Institutes of Communicable Disease, Department of Microbiology, Delhi.</p> <p>b) National Institute of Virology, Pune</p> <p>c) Centre of Advanced Research in Virology, Christian Medical College, Vellore.]</p> <p>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</p> <p>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.</p>	
3		Answer any FOUR of the followings	12M
3	a)	<p>Enlist licences (with form number) for retail and wholesale of Schedule C,C1 and Sch 'X' drugs under D &C Act, 1940.</p> <p>i) License on Form 21 is issued for retail sale of Allopathic drugs specified in Schedule C & C(1).</p> <p>ii)License on Form 21-B is issued for wholesale of Allopathic drugs specified in Schedule C &C(1).</p> <p>iii)License on Form 20-F is issued for retail sale of drugs specified in Schedule 'X'.</p> <p>iv)License on Form 20-G is issued for wholesale of drugs Specified in Schedule 'X'</p>	3M
3	b)	<p>Write formula for calculation of retail price of drug formulation and explain the term involved in it as per Drugs (Price Control) Order , 1995.</p> <p>By applying the following formula, the retail price of the formulation is calculated by the Government.</p> <p>R.P.= (M.C.+ C.C.+ P.M. + P.C.) x (1+ MAPE/100) + ED</p> <p>Where,</p> <p>R.P.:- Means retail price.</p> <p>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.</p>	3M (Formula-1M Explanati on- 2M)



		<p>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> <p>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> <p>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.</p> <p>MAPE :- Maximum allowable post manufacturing expenses.</p> <p>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.</p> <p>E.D.:- means excise duty. In case of an imported formulation, the landed cost shall form the basis for fixing its price. Margin not exceeding 50% of the landed cost to cover selling and distribution expenses including importers profit is also taken into account.</p>	
3	c)	<p>Write the constitution of Pharmacy Council of India</p> <p>Pharmacy Act, 1948 provides for the constitution of a Central Council (Pharmacy Council of India) under section 3 of Pharmaceutical Legislation by Central Government. The council consists of following members.</p> <p>ELECTED MEMBERS</p> <p>1) Six members, among whom there shall be at least one teacher of each of the subjects of Pharmaceutical; Chemistry, Pharmacy, Pharmacology and Pharmacognosy elected by the University Grants Commission, from among persons on the teaching staff of an Indian university or a college affiliated thereto which grants degree or diploma in pharmacy.</p> <p>2) One member elected by the members of Medical Council of India amongst themselves.</p> <p>3) One member from each state elected by the members of each State Council, amongst themselves shall be registered pharmacist.</p> <p>NOMINATED MEMBERS</p> <p>1) Six members nominated by the Central Government of whom at least four shall be possessing degree or diploma in pharmacy and practicing pharmacy or pharmaceutical chemistry.</p>	3M



		<p>2)A representative of UGC and representative of All India Council for Technical Education.</p> <p>3)One member from each state nominated by State Government, shall be registered pharmacist.</p> <p>EX-OFFICIO MEMBERS</p> <p>Director General of Health Services</p> <p>Drug Controller of India</p> <p>Director of Central drugs Laboratory.</p>	
3	d)	<p>Define under D&C Act ,1940 and Rules</p> <p>(i)Drug : it includes</p> <p>i) All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;</p> <p>ii) Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of[vermin] or insects which cause disease in human beings or animals may be specified from time to time by the Central Government by notification in the official Gazette;</p> <p>iii) All substances intended for use as components of a drug including empty gelatin capsules; and</p> <p>iv) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorders in human beings or animals, may be specified from time to time by the Central Government by notification in the official Gazette, after consultation with the Board;</p>	<p>3M</p> <p>(Each definition 1^{1/2} M)</p>



		<p>(ii) New Drug: it includes</p> <p>(i) A new substance of chemical, biological or biotechnological origin in bulk or prepared dosage form used for prevention, diagnosis, or treatment of disease in man or animals, which except during local clinical trials has not been used in the country to any significant extent</p> <p>(ii) A drug already approved by the Licensing authority for certain claims, which is now proposed to be marketed with modified or new claims namely indications dosage, dosage form.</p> <p>(iii) A fixed dose combination of two or more drugs, individually approved earlier for certain claims which are now proposed to be combined for the first time in a ratio or if the ratio of ingredients in an already marketed combinations is proposed to be changed with certain claims.</p>	
3	e)	<p>Give any three offences and penalties under NDPS Act, 1985</p> <p>Offences and penalties are-</p> <p>1. Punishment for contravention in relation to poppy straw. -Whoever, in contravention of any provisions of this Act or any rule or order made or condition of a license granted thereunder, produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw or removes or does any act in respect of warehoused poppy straw shall be punishable,-</p> <p>(a) where the contravention 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;</p> <p>(b) where the contravention 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;</p> <p>(c) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees.</p>	1M each, any 3



Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupee

2. Punishment for contravention in relation to coca plant and coca leaves.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, cultivates any coca plant or gathers any portion of a coca plant or produces, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses coca leaves shall be punishable with rigorous imprisonment for a term which may extend to ten years or with fine which may extend to one lakh rupees.

3.Punishment for contravention in relation to prepared opium :-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted there under ,manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses prepared opium shall be punishable,

(a) where the contravention 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) where the contravention 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; or

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

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

4. Punishment for contravention in relation to opium poppy and opium: -Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted there under, cultivates the opium poppy or produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses opium shall be punishable,

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

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees;

(c) in any other case, with rigorous imprisonment which may extend to ten years and with fine which may extend to one lakh rupees.

5. Punishment for embezzlement of opium by cultivator. -Any cultivator licensed to cultivate the opium poppy on account of the Central Government who embezzles or otherwise illegally disposes of the opium produced or any part thereof, shall be punishable 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 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.

6. 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.

7.Punishment for contravention in relation to manufactured drugs and preparations.-

Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any manufactured drug or any preparation containing any manufactured drug shall be punishable,

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

8.Punishment for contravention in relation to psychotropic substances:-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any psychotropic substance shall be punishable,

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

9. Punishment for illegal import in to India, export from India or transshipment of narcotic drugs and psychotropic substances.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license or permit granted or certificate or authorization issued thereunder, imports into India or exports from India or transships any narcotic drug or psychotropic substance shall be punishable,-

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

10. Punishment for external dealings in narcotic drugs and psychotropic substances in contravention of section 12.-Whoever engages in or controls any trade whereby a narcotic drug or a psychotropic substance is obtained outside India and supplied to any person outside India without the previous authorization of the Central Government or otherwise than in accordance with the conditions (if any) of such authorization granted under section 12, shall



be punishable 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 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.

11. Punishment for allowing premises, etc., to be used for commission of an offence.-

Whoever, being the owner or occupier or having the control or use of any house, room, enclosure, space, place, animal or conveyance, knowingly permits it to be used for the commission by any other person of an offence punishable under any provision of this Act, shall be punishable with the punishment provided for that offence.

12. Punishment for contravention of orders made under section 9A. –If any person contravenes an order made under section 9A, he shall be punishable 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:

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding one lakh rupees.

13. Punishment for certain acts by licensee or his servants.-If the holder of any license, permit or authorization granted under this Act or any rule or order made thereunder or any person in his employ and acting on his behalf-

(a) omits, without any reasonable cause, to maintain accounts or to submit any return in accordance with the provisions of this Act, or any rule made thereunder;

(b) fails to produce without any reasonable cause such license, permit or authorization on demand of any officer authorized by the Central Government or State Government in this behalf;

(c) keeps any accounts or makes any statement which is false or which he knows or has reasons to believe to be incorrect; or

(d) wilfully and knowingly does any act in breach of any of the conditions of license, permit or authorization for which a penalty is not prescribed elsewhere in this Act,

he shall be punishable with imprisonment for a term which may extend to three years or with fine or with both.

14. Punishment for consumption of any narcotic drug or psychotropic substance.-



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

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

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

15. Punishment for financing illicit traffic and harbouring offenders.-Whoever

indulges in financing, directly or indirectly, any of the activities specified in sub-clauses (i) to (v) of clause (viii) of section 2 or harbours any person engaged in any of the aforementioned activities, shall be punishable 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].

16. Punishment for contravention of section 8-A-Whoever contravenes the provision of section 8-A shall be punishable with rigorous imprisonment for a term which shall not be less than three years but which may extend to ten years and shall also be liable to fine.

17. Punishment for attempts to commit offences.-Whoever attempts to commit any offence punishable under this Chapter or to cause such offence to be committed and in such attempt does any act towards the commission of the offence shall be punishable with the punishment provided for the offence.

18. Punishment for abetment and criminal conspiracy.-(1) Whoever abets, or is a party to a criminal conspiracy to commit an offence punishable under this Chapter, shall, whether such offence be or be not committed in consequence of such abetment or in pursuance of such criminal conspiracy, and notwithstanding anything contained in section 116 of the Indian Penal Code (45of 1860), be punishable with the punishment provided for the offence.

(2) A person abets, or is a party to a criminal conspiracy to commit, an offence, within the meaning of this section, who, in India abets or is a party to the criminal conspiracy to the



commission of any act in a place without and beyond India which-

- a) would constitute an offence if committed within India; or
- b) under the laws of such place, is an offence relating to narcotic drugs or psychotropic substances having all the legal conditions required to constitute it such an offence the same as or analogous to the legal conditions required to constitute it an offence punishable under this Chapter, if committed within India.

19. Preparation.-If any person makes preparation to do or omits to do anything Which constitutes an offence punishable under any of the provisions of [sections 19,24 and 27A and for offences involving commercial quantity of narcotic drug or psychotropic substance and from the circumstances of the case, it may be reasonably inferred that he was determined to carry out his intention to commit the offence but had been prevented by circumstances independent of his will, he shall be punishable with rigorous imprisonment for a term which shall not be less than one-half of the minimum term (if any), but which may extend to one-half of the maximum term, of imprisonment with which he would have been punishable in the event of his having committed such offence, and also with fine which shall not be less than one-half of the minimum amount (if any), of fine with which he would have been punishable, but which may extend to one-half of the maximum amount of fine with which he would have ordinarily (that is to say in the absence of special reasons) been punishable, in the event aforesaid:

Provided that the court may, for reasons to be recorded in the judgment, impose a higher fine.

20. Enhanced punishment for offences after previous conviction.-(1) If any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable under this Act is subsequently convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, an offence punishable under this Act with the same amount of punishment shall be punished for the second and every subsequent offence with rigorous imprisonment for a term which may extend to one-half of the maximum term of imprisonment and also be liable to fine which shall extend to one-half of the maximum amount of fine.

(2) Where the person referred to in sub-section (1) is liable to be punished with a minimum term of imprisonment and to a minimum amount of fine, the minimum punishment for such



person shall be one-half of the minimum term of imprisonment and one-half of the minimum amount of fine:

Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding the fine for which a person is liable.

(3) Where any person is convicted by a competent court of criminal jurisdiction outside India under any corresponding law, such person, in respect of such conviction, shall be dealt with for the purposes of sub-sections (1) and (2) as if he had been convicted by a court in India.]

21-A-Death penalty for certain offences after previous conviction.-(1) Notwithstanding anything contained in section 31, if any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable under³⁹[section 19, section 24, section 27-A and for offences involving commercial quantity of any narcotic drug or psychotropic substance] is subsequently convicted of the commission of or attempt to commit or abetment of or criminal conspiracy to commit an offence relating to-

(2) where any person is convicted by a competent court of criminal jurisdiction outside India under any law corresponding to the provisions of [section 19, section 24 or section 27 A and for offences involving commercial quantity of any narcotic drug or psychotropic substance], such person, in respect of such conviction, shall be dealt with for the purposes of sub-section (1) as if he had been convicted by a court in India.]

22. Punishment for offence for which no punishment is provided.-Whoever contravenes any provision of this Act or any rule or order made, or any condition of any license, permit or authorization issued thereunder for which no punishment is separately provided in this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine, or with both.

3

f)

Explain essential requirements for Bonded Laboratory

Following are the requirements of the bonded laboratory

- 1) The spirit store (if a distillery or rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory.)
- 2) Room or rooms for manufacture medicinal preparations.
- 3) One or more rooms for storing finished medicinal preparations.

3M



- 4) A separate room or arrangement for manufacture of toilet preparations.
- 5) The storage room for the finished toilet preparations.
- 6) Accommodation near the entrance for the officer in-charge with necessary furniture.
- 7) Every room in the bonded laboratory should bear a board indicating the name of the room & serial number.
- 8) The pipes form sinks or wash basins in the laboratory should be connected with the general drainage of the laboratory.
- 9) The arrangements of gas & electric connections should be such that their supply can be cut off at the end of day's work.
- 10) Every window in the laboratory would specific arrangement of malleable iron rods of prescribed dimensions and the window should be covered on the inside with strong wire netting of mesh not exceeding 25mm.
- 11) There shall only one entrance to the bonded laboratory & one door to each of its compartments. All the doors shall be secured with excise ticket locks in the absence of the officer-in-charge.
- 12) All vessels intended to hold alcohol & other liquid preparations should bear distinctive serial no. with their full capacity marked individually.
- 13) 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.

4 **Answer any FOUR of the followings**

12M

4 **a) Write qualifications required for government analyst as per D & C Act, 1940.**

3M

A person appointed as a Government Analyst should possess the following qualifications-

- 1.A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 5 years post-graduate experience in the testing of drugs; or
- 2.A post graduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 3 years experience in the testing of drugs.

or



		<p>3. Associate ship Diploma of the Institution of Chemists (India) with “Analysis of Drugs and Pharmaceuticals” as one of the subjects with not less than 3 years’ experience in the testing of the drugs in a laboratory under the control of</p> <p>a) A government Analyst</p> <p>b) Head of institution or testing laboratory approved for the purpose by the appointing laboratory.</p>	
4	b)	<p>Give the constitution of Joint State Pharmacy Council under Pharmacy Act 1948</p> <p>Joint state pharmacy council consist of the following members:</p> <p>Elected Members-</p> <p>1) As provided in the agreement not less than 3 and not more than 5 members elected amongst the registered pharmacist of each participating state.</p> <p>2) One member elected by the members of each Medical Council from amongst themselves, of each participating state.</p> <p>Nominated Members-</p> <p>As agreement provides, not less than two and not more than four members nominated by each participating State Government of whom more than half should possess degree or diploma in pharmacy or pharmaceutical chemistry or be a registered pharmacist.</p> <p>Ex-Officio Members-</p> <p>1) Chief administrative medical officer of each participating State</p> <p>2) Officer incharge of drugs control organization of each participating state; appointed under D & C Act 1940.</p> <p>3) Government analyst appointed under D & C, 19740 of each participating state.</p> <p>Where two or more States enter into an agreement, whereby the State Pharmacy Council of one State serves the needs of other State or States, the membership of the State Pharmacy Council may be augmented, by NMT two persons nominated by each of the State Government of which at least one always have a degree or diploma in Pharmacy or Pharmaceutical Chemistry or Registered Pharmacist.</p>	3M



4	c)	<p>Define the following under NDPS Act, 1985</p> <p>i) Coca Leaf: It includes:</p> <p>i)The leaf of coca (Erythroxyton) plant (excluding the leaf from which all ecognine, cocaine and any other ecognine alkaloids have been removed).</p> <p>ii)Any mixture thereof with or without any neutral material and does not include any preparations containing less than 0.1% of cocaine.</p> <p>ii) Opium: It means the coagulated juice of the opium poppy and it's mixture with or without neutral material, (excluding the preparations containing less than 0.2 % of morphine)</p> <p>iii) Cannabis: It includes the following:</p> <p>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.</p> <p>ii) Ganja, which comprises of flowering or fruiting tops of the cannabis plant (excluding seeds and leaves not accompanied by the tops)</p> <p>iii) Any mixture with or without any neutral material of ganja or charas or any drink prepared from them.</p>	3M (Each definition 1M)
4	d)	<p>Define “Misbranded drugs” under Drugs and Cosmetic Act, 1940</p> <p>A drug shall be deemed to be misbranded:</p> <p>1)If it is so colored, coated, powdered or polished that, damage is concealed or if it is made to appear of better or greater therapeutic value than it really is or</p> <p>2)If it is not labeled in the prescribed manner, or</p> <p>3)If it’s label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.</p>	3M



4	e)	<p>State the procedure for dispatch of sample from drug inspector to government analyst.</p> <p>1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under subsection(4) of section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18,in an outer cover addressed to the Government Analyst.</p> <p>2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.</p>	3M
4	f)	<p>Define Repatriate and UGC as per Pharmacy Act, 1948</p> <p>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.</p> <p>UGC: (University Grants Commission): It means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956.</p>	3M (Each Definition 1 ^{1/2} M)
5		<p>Attempt any FOUR of the followings</p>	12M
5	a)	<p>Give the procedure to be followed for the movement of goods from one warehouse to another warehouse under MTP (E.D.) Act,1955.</p> <p>Procedure for the movement of goods from one warehouse to another</p> <p>1)When the goods are to be removed from one warehouse to another, the consignor or the consignee should enter into a bond with surety or sufficient security.</p> <p>2) Such bond shall be furnished to the officer-in-charge of the warehouse of removal or the warehouse of destination as the case may be.</p> <p>3) Such bond shall remain valid until officer-in-charge of the warehouse of removal has received a re-warehousing certificate (stating that the goods have been re-warehoused) form the officer-in-charge of warehouse of destination.</p> <p>4) The consignor should make an application in triplicate for removal of goods from one</p>	3 Marks



warehouse to another warehouse to the officer-in-charge of the warehouse together with other necessary information as the Excise Commissioner may require at least 24 hours before the removal of goods.

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

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

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

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

b) Define as per Drugs (Price control) order, 1995

(i)Ceiling price :- It means a price fixed by the Government for Scheduled formulations according to the provisions of DPCO.

(ii)Scheduled formulation:- Schedule formulation means a formulation containing any bulk drug specified in the first schedule, either individually or in combination with other drugs. , including one or more than one drug or drugs not specified in the First Schedule and sold under the generic name

(iii) Retail price:- retail price means the retail price of drug arrived at or fixed in accordance with the provision of Drugs (Prices Control) Order, 1995 and include a ceiling price.

**1 Mark
for Each
definition**



<p>c)</p>	<p>What are the rules prescribed by the state government in relation to “Possession and sale of poisons under Poison Act, 1919.</p> <p>Possession for sale & sale of any Poison-</p> <p>The State Government may by making rules, regulate the possession and possession for sale of poisons whether wholesale or retail, within whole or specified areas of their territories.</p> <p>The State Govt. has power to make such rules in this connection which may provide for -</p> <ol style="list-style-type: none">1) The grant of licenses for possession and sale of any specified poison for sale, whether wholesale or retail & fixing of the fees to be charged for such licenses.2) The classes of persons to whom the licenses for possession and possession for sale are be granted.3) The classes of persons to whom such poison may be sold.4) The maximum quantity of any poison that may be sold to a person.5) The maintenance of the registers for sale of poisons and inspection of the same.6) Safe custody of poisons and the labelling of the vessels, packages or coverings in which such poison is sold or stored for sale.7) Inspection & examination of any such poison possessed for sale by any vendor.8)The State Govt. has power to make rules regarding the possession of any specified poison in local area where such poison can be used for murders or for poisoning cattle & in such local area where such occurrences are very frequent.	<p>3 Marks</p>
<p>d)</p>	<p>Write any three offences and penalties under Medicinal and Toilet Preparation Act,1955.</p> <ol style="list-style-type: none">1. a) Contravention of any of the provisions relating to the terms & conditions of a license granted under the Act, orb) Failure to pay any duty of excise payable under this Act, orc) Failure to supply required information or supplying false information ord) Attempt to commit or abet any of the above offence <p>Penalty- Imprisonment upto 6 month or Fine upto 2000/- or both</p> <ol style="list-style-type: none">2. Connivance by any owner or occupier of land or by any agent of such owner or	<p>3M</p> <p>(1Mark Each, any 3)</p>



- 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.



	<p>Penalty- Fine upto 1000/- & confiscation of the goods related with this offence.</p> <p>14. Disclosure of information by Excise officers learned by him in his official capacity.</p> <p>Penalty- Fine upto 1000/-</p>	
e)	<p>Write a short note on Drug Prices Equalization Account (DPEA) as per Drugs (Price control) order, 1995?</p> <p>Drug Prices Equalization Account (DPEA).</p> <p>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.</p> <p>The amount from DPEA shall be utilized for:</p> <p>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.</p> <p>ii) Meeting the expenses incurred by the Government in discharging the functions under this provisions.</p> <p>iii) Promoting higher Education and Research in Pharmaceutical Sciences and Technology.</p>	3 Marks
f)	<p>Write the scope and objectives of Pharmaceutical Legislation in India.</p> <p>Objectives-</p> <p>1) To promote health care by regulating the manufacture, supply & distribution of good quality drugs.</p> <p>2) To make these drugs available to the public at reasonable prices & through qualified person.</p> <p>3) To safeguard the people from misleading & false advertisements relating to drugs & remedies</p> <p>4) To regulate the profession of pharmacy.</p> <p>5) To promote the Indigenous research technology</p>	1^{1/2} marks



		<p>Scope of pharmaceutical legislation of India</p> <p>1) It is related with legal system which regulates the conduct of pharmacy business & practice of profession of pharmacy.</p> <p>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.</p> <p>3) It helps the pharmacist to understand their legal & ethical responsibilities & their by avoid the danger of unnecessary legal proceedings.</p> <p>4) The patient should get the drugs of good quality which are tested & evaluated for</p>	1^{1/2} marks
6		Attempt any FOUR of the followings	16M
	a)	<p>Write the ex-officio and nominated members of Drug Technical Advisory Board (D.T.A.B.)</p> <p>Ex-officio members:-</p> <p>i) The Director-General of Health Services, who is the chairman of the Board.</p> <p>ii) The Drug Controller of India</p> <p>iii) The Director of the Central Drug Laboratory, Calcutta</p> <p>iv) The Director of the Central Research Institute, Kasauli</p> <p>v) The Director of the Central Drug Research Institute, Lucknow.</p> <p>vi) The Director of the Indian Veterinary Research Institute, Izatnagar</p> <p>vii) The President, Pharmacy Council of India</p> <p>viii) The President, Medical Council of India</p> <p>Nominated Members -Following members nominated by Central Government.</p> <p>i) Two persons from among persons who are in-charge of the drugs control in the states</p> <p>ii) One person from the pharmaceutical industry.</p> <p>iii)Two Government Analysts.</p>	2^{1/2} Marks 1^{1/2} marks



<p>b)</p>	<p>Which operations are controlled by the Central and State Govt. under Narcotic and Psychotropic Substances act, 1985? (any 4 each)</p> <p>The operations controlled by Central Government under N.D.P.S. Act, 1985.</p> <ol style="list-style-type: none">1) Government shall fix time to time the limits within which licenses may be given for cultivation of opium poppy.2) All opium, the product of land cultivated with opium poppy shall be delivered by cultivators to Officers authorized on behalf of Central Government.3) Central Government may from time to time fix the price to be paid to the cultivators for the opium delivered.4) The rules may prescribe the forms & conditions of licenses for the manufacture, possession, production, purchase, sale, transport, import, export, consumption or use of Psychotropic substances. Fix fees may be charged for such licenses.5) The rules may prescribe the forms & conditions of licenses for cultivation of the opium poppy and production & manufacture of opium. The rule also prescribes the fees that may be charged therefore.6) The rules may prescribe forms & conditions of licenses for manufacture of manufactured drugs & fees that may be charged therefore.7)The rules may provide for the examination and classification, according to the quality and consistence of the opium received at the factory and the deductions from or additions to the standard price to be made in accordance with the result of examinations.8) The rules may prescribe that opium shall be weighed, examined & classify according to its quality & consistency by the officers authorized in this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator.9) Rules may require that delivered opium by cultivator, if found as a result of examination in the Central Government factory to be adulterated, may be confiscated by the officers authorized in this behalf.10) The rules may prescribe the ports & other places at which any kind of narcotic drugs or psychotropic substances may be imported into India or exported from India or transhipped.	<p>2M , any4</p>
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	<p>The operations controlled by State Government under N.D.P.S. Act, 1985.</p> <p>i) Provide that the State Government shall fix from time to time the limits within which licenses may be given for any cultivation of cannabis plant.</p> <p>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.</p> <p>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.</p> <p>iv) Empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered.</p> <p>v)Prescribe the forms and conditions of licenses or permits licenses 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).</p> <p>vi) Empower the state government to declare any place to be warehouse wherein it shall 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.</p>	<p>2M, any4</p>
<p>c)</p>	<p>What particulars that should appear on the label of the ophthalmic preparations as per D & C Act, 1940?</p> <p>Ophthalmic solutions and suspensions : the following additional particular shall be shown on the label of container</p> <p>i)The statement ‘use the solution within one month after opening the container’.</p> <p>ii)Name and concentration of the preservative used.</p> <p>iii)The words ‘NOT FOR INJECTION.’</p> <p>iv)Special instructions regarding storage, wherever applicable.</p> <p>v)A cautionary legend reading as:-</p> <p>WARNING :-</p> <p>i)If irritation persists or increases, discontinue the use and consult physician.</p>	<p>4 Marks</p>



	<p>ii) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate solution.</p> <p>Ophthalmic ointments :</p> <p>Special instructions regarding storage wherever applicable.</p> <p>WARNING : If irritation persists or increases, discontinue the use and consult physician.</p>	
d)	<p>Write duties of drug inspector in relation to manufacture of drugs.</p> <p>1) To inspect atleast twice a year, all premises licensed for manufacturing of drugs within the area allotted to him & to satisfy whether the conditions of license & provisions of the act and rules thereunder are being observed or not.</p> <p>2) To inspect premises licensed for manufacturing of drugs, specified in Schedule-C & C(1) & to observe process of manufacturing, means employed for standardization & testing of drug & storage conditions & qualification of technical staff and employee & all other details of location, construction, administration of establishment, other things which may likely to affect potency & purity of the product.</p> <p>3) To sent after each inspection a detailed report of inspection to the controlling authority with which conditions of license and provisions of the act & the rules thereunder being observed and which being not observed.</p> <p>4) To take sample of drugs manufactured in the premises and sent them for test or analysis.</p> <p>5) To check all the records & registers required to be maintained under the rules.</p> <p>6) To institute prosecutions, in respect of breach of the act and rules.</p>	4 Marks
e)	<p>Discuss the offences and penalties under:</p> <p>(i)The poisons Act, 1919 (any 2)</p> <p>Offences:</p> <p>1) Unlawful importation of any poison.</p> <p>2) Unlawful possession & sale of poison.</p> <p>3) Breaking of any condition of license for import of any poison granted to him</p> <p>Penalties:-</p> <p>1) Imprisonment 3 month or with fine- 500 Rs or Both on 1st conviction</p>	2Marks , any2



	<p>2) Imprisonment 6 month or with fine- 1000 Rs or Both on subsequent conviction.</p> <p>3) The poison in connection with offence, together with the packages, vessels, covering is liable for confiscation</p> <p>(ii) Medicinal Termination of pregnancy Act, 1971 (any 2)</p> <p>As per the latest amendments in M.T.P. Act, 1971</p> <p>i) The termination of a pregnancy by a person who is not a registered medical practitioner shall be an offence punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.</p> <p>ii) Whoever terminates any pregnancy in a place other than that mentioned in sec.4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.</p> <p>iii) Any person being owner of a place which is not approved under clause(b) of sec.4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.</p>	<p>2Marks , any2</p>
<p>f)</p>	<p>Give the function under NDPS Act, 1985</p> <p>(i) Narcotic commissioner and</p> <p>1) Supervision of cultivation of the opium poppy</p> <p>2) Production of opium</p> <p>3) Other functions as may be entrusted to him by the Central Government.</p> <p>(ii) Narcotic Drug and Psychotropic Substances Consultative Committee</p> <p>committee shall advise the Central Government on the matters relating to the administration of this Act.</p>	<p>2M</p> <p>2M</p>