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 (2x8)**
1	**a)**	**Give Ex-officio members of Joint state Pharmacy Council.** 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. 3) Government Analyst appointed under D&C Act, 1940 of each participating state.	**2 M**
1	**b)**	**Define Advertisement Under DMR 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.	**2 M**
1	**c)**	**State any two measures for combating abuse of narcotic drugs and illicit traffic.** Central Government under the provisions of this Act, may take the measures with respect to all or any of the following matters: - i. Co-ordination of actions by various officers, State Government and other authorities under this act or under any other law for the time being in force relating to enactment of the Act. ii. Obligations under the international conventions. iii. Assistance to the concerned authorities in foreign countries and concerned international organizations regarding prevention and suppression of illicit traffic and narcotic drugs and psychotropic substances. iv. Controlling the abuse of narcotic drugs and psychotropic substances. v. Identifying, treating, rehabilitation, education and social re-interaction of addicts. vi. Supplying drugs to addicts where such supply is a medical necessity. vii. Such other matters for effective implementation of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic	**1 M for each, Any two points**

		therein.	
1	**d)**	**How retails price of formulation is calculated under DPCO Act-1995.** By applying the following formula, the retail price of the formulation is calculated: R.P. = (M.C.+ C.C.+ P.M. + P.C.) **x** (1+ MAPE/100) + ED Where: **R.P.: -** Means retail price. **M.C.:-** Means material cost. **C.C.:-** Means conversion cost. **P.M**.:- Means the cost of packing material. **P.C.:-** Means packing charges. **MAPE: -** Maximum allowable post manufacturing expenses. MAPE shall not exceed 100% for indigenously scheduled formulations. **E.D.:-** Means excise duty.	**1 M for Formula,** **1 M for Full Form**
1	**e)**	**Give any two difference between Bonded and Non-bonded Laboratory:**	**1 M for Each, Any two points**

Sr No	Bonded Laboratory	Non - Bonded Laboratory
1	It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has not been paid.	It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has been paid.
2	Excise duty payable on removal of goods from bonded laboratory.	Excise duty payable at the time of spirit purchase.
3	Bonded laboratory to function under excise staff	No excise staff is required.

		4	License required should be obtained from Excise Commissioner.	License required should be obtained from the officer as the State Government may authorize on this behalf.	
		5	Alcohol on which duty has not been paid shall be used under the excise supervision.	Only the alcohol on which duty has already been paid shall be used.	
		6	Suitable for large scale manufacture.	Suitable for small scale manufacture.	
1	**f)**	**Define Guardian and Owner under MTP Act, 1971.** **Definition of "Guardian"** means a person having the care of a minor or a lunatic. OR Person having the care of the 'person of minor' or a 'mentally ill person' {Sec. 2(a)} **Definition of "Owner"** Owner in relation to place, means any person who is the administrative head or otherwise responsible for the working or maintenance of such Hospital or clinic.			**1 M** **1 M**
	g)	**Give the objectives of DMR Act, 1954** Objectives:- i) To control certain types of advertisements relating to drugs & ii) To prohibit certain kinds of advertisement relating to Magic Remedies, which falsely claim & mislead public. iii) To provide matter related therewith.			**2 M**
1	**h)**	**Mention any four conditions of license for sale of Schedule H and schedule X drug under D and C, 1940.** **Sale of Drugs specified in Schedule H and schedule X:** 1)Substances specified in Schedule H and schedule X should not be sold by retail and sold only in accordance with the prescription of RMP. In case of substances specified in			**2 M**

		Schedule X, the prescription should be duplicate, one copy of which is retained by licensee and preserved for at least for two years. 2)Drugs from Schedule H and schedule X, supplied to Registered Medical Practitioner, Hospitals, Dispensaries and Nursing Homes, shall be supplied only against signed written order and such order should be preserved for at least for two years. 3)A prescription of RMP against which drugs from Schedule H or Schedule X, supplied should: i)Be in writing and signed by the person giving it, with his usual signature and be dated. ii)Specify the name and address of the patient or name and address or owner of the animal if drug is for veterinary use. iii)Indicate the total amount of drugs supplied and doses to be taken.	
1	**i)**	**State what does following prescribe under D and C Act, 1940:** **i) Form 20A** **ii) Form 20G** (i) **Form 20A-** License issued in Restricted area For the sale of Drugs other than sch. C, C(1) and X. (ii) **Form 20G-** License issued for Wholesale of Drugs specified in Sch. X	**1 M** **1 M**
1	**j)**	**Discuss any two functions of P. C. I.** **Functions of PCI:-** 1) To prescribe the minimum standard of education required for qualification as a Pharmacist (This can be provided by making rules as Education Regulation which prescribes minimum qualification for admission, duration of course, details of syllabus, practical training, & examination, minimum facilities required for the conduct of course, examination & practical training) **2)** To regulate minimum educational standard. (for this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy & report on the facilities available & decides whether the institution should be	**1 M each, Any two**

		recognized or not) **3)** To recognize qualification granted outside the territories to which Pharmacy Act,1948 extends for the purpose of qualifying for registration under the said Act **4)** To compile & maintain a Central Register for Pharmacist containing names of all persons for the time being entered in the state register. **5**) Any other functions that may be assigned to the Central Council in the furtherance of the objective of the Pharmacy Act,1948.	
1	**k)**	**Give objectives of Pharmacy Act, 1948** The main objective of Pharmacy Act is- i) To regulate the profession and practice of pharmacy and ii) To raise the status of profession of pharmacy in India.	**2 M**
1	**l)**	**Define "Formulation"** **Formulation** means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but it does not include - (a) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines. (b) any medicine included in the Homeopathic system of medicine; and (c) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.	**2 M**
2		**Answer any FOUR of the followings:**	**12 (4X3)**
2	**a)**	**What is DEC? Give its recommendations.** The Indian Government formed a 'Drug Enquiry Committee' (D.E.C. or Chopra Committee) in 1930 under the Chairmanship of Lt. Col. R. N. Chopra to study problems related to drugs in India. Following are some important recommendations of DEC- 1) Formation of Central Pharmacy Councils & State Pharmacy Councils which would	**1M**

		look after the education & training of professionals. These councils would maintain the register containing the names & addresses of the Registered Pharmacists. 2) Creation of Drug Control Machinery (Departments) at the Centre with the branches in all the states. 3) Establishment of well-equipped Central Drug Laboratory (CDL) with competent staff and experts for an efficient and speedy working of Drug Control Department. It was also suggested that the small laboratories would work under the guidance of Central Drug Laboratory.	**2M, any 2**
2	**b)**	**Define Adulterated Drug under D and C Act, 1948.** 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 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.	**3 M**
2	**c)**	**Define Magic Remedies and give exempted advertisement** **Magic Remedies**- It includes Talisman, Mantra, Kavach and any other charm claiming to possess miraculous power, i. for diagnosis, treatment and prevention of any disease in human being and in animal or ii. for affecting or altering the structure or organic function of the body of human being or animal. **Classes of exempted advertisements**: 1. Any advertisements relating to the drugs printed or published by the Government or any other person with prior permission of the Government.	**1 M for Definition** **2 M, Any 4**

		2. Any advertisement relating to a drug which is sent confidentially in the prescribed manner to registered medical practitioner. 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. 4. Displayed signboards or notices by registered medical practitioners on his premises indicating that the treatment is undertaken for any any disease, disorders or conditions specified in the schedule to this Act or in the rules made under this Act. 5. Advertisements relating to the drugs which comply with the required conditions as follows: (a) Leaflets or literature along with packing of drugs; or advertisements of drugs in medicinal, pharmaceutical, scientific and technical journals (b) Therapeutic index or price list published by licensed manufacturer, importer or distributer of drugs or medical literature distributed by medical representatives. With conditions that: i) The advertisement should contain only the information required for the guidance of registered medical practitioner regarding: (a) therapeutic indications; (b) route of administration; (c) dosage and side effects of such drug or drugs; and (d) the precautions to be taken in treatment with the drug ii) The distribution of such literature should be given to registered medical practitioner, dispensaries, hospitals, medical and research institutions, chemists and druggists or pharmacies.	
2	**d)**	**Discuss the operations controlled by Central government under NDPS Act, 1985.** i) Government shall fix from time to time the limits within which licences may be given for the cultivation of opium poppy. ii) All opium, the product of land cultivated with the opium poppy shall be delivered by	**½ M each, any6**

		the cultivators to the officers authorized on behalf of Central Government. iii) The Central Government may from time to time fix the price to be paid to the cultivators from the opium delivered. iv) The rules may prescribe the forms and conditions of licenses or permits for the manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances. The rules may also prescribe the authorities granted and the fees that may be charged therefor. v) The rules may prescribe the forms and conditions of licences for cultivation of the opium poppy and for the production and manufacture of opium. The rules may also prescribe the fees that may be charged therefore the authorities by which such licences may be granted, withheld, refused or cancelled and the authorities before which appeals against the orders of withholding, refusal or cancellation of licences shall lie. vi) The rules may prescribe that opium shall be weighed, examined and classified according to its quality and consistence 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. vii) The rules may provide for the weighment, examination and classification according to the quality and consistence of the opium received at the factory and the deductions from or addition to the standard price to be made in accordance with the result of such examinations. viii)The rules may prescribe the forms & conditions of license for the manufacture of manufactured drugs, the authorities by which such licenses may be granted & fees that may be charged therefore; ix)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. x)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.	

2	**e)**	**Give offences and Penalties under Pharmacy Act, 1948.** **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. **2) Dispensing by unregistered persons:** The persons other than registered pharmacist dispensing any medicine for patients is liable for punishment with imprisonment upto six months or with fine upto one thousand rupees or with both. **3) Failure to surrender certificate of registration:** Is also punishable with fine upto fifty rupees. **4) Obstructing State Pharmacy Council Inspectors :-** Penalties :- Shall be deemed guilty of an offence & may be punished with imprisonment upto six month or fine upto 1000 Rs or both	**1 M each, any 3**
2	**f)**	**State the various rules prescribed by State Govt. for possession, possession for sale and for sale of poisonous substances under Poison Act, 1919.** The State Govt. may regulate the Possession & Sale of poison within the state. The sale may be wholesale or retail. The rules may be applicable for the whole or any part of the territories under the administration of the state. Such a rules may provide for- i) Grant of licenses for the possession of any specified poison for sale, either wholesale or retail. ii) Fixing of fees to be charged for such a licenses iii) The classes of persons to whom the licenses for the possession & Sale of poisons are to be granted.	**3 M**

		iv) Maximum quantity of such poison which may be sold any person v) Maintenance of Register for the sale of poisons & inspection of the same. vi) Safe custody of poisons & the labelling of the vessel, coverings or packages in which such poison is sold or stored for sale. vii) Inspection & Examination of any such poison possessed for sale by any vendor**.**	
3		**Answer any FOUR of the followings:**	**12M(3x4)**
3	**a)**	**Discuss the role of DTAB with its constitution (only Ex-officio members).** **Role of DTAB:** i)To advice the Central Govt. & state Govt. On technical matters arising out of the administration of this Act & ii)To carry out the other functions assigned to it by this act. **Ex-officio members of DTAB:** 1) The Director General of Health Services, who shall be Chairman of the board. 2) The Drugs Controller of India. 3) The Director of the Central Drugs Laboratory, Calcutta. 4) The Director of the Central Research Institute, Kasauli. 5) The Director of Indian Veterinary Research Institute, Izatnagar. 6) The Director of Central Drug Research Institute, Lucknow. 7) The President of Medical Council of India. 8) The President of the Pharmacy Council of India.	**1 M** **2 M**
3	**b)**	**Describe labeling provisions under D and C Act, 1940 for the following:** **i) Hair dyes ii) Vaccines** **(i)Labeling Provisions of Hair dyes** Hair dyes containing paraphenylene diamine or other coal tar dyes or coal tar intermediates should be labeled with the following words (On outer and the inner labels). ‘**’Caution:** This product contains ingredients which may cause skin irritation in certain cases & so a preliminary test according to the accompanying directions should first be made. The product should not be used for dyeing the eye-lashes or eye-brows; as such use	**1½ M**

		may cause blindness''. In addition, the following instructions in English & other local language should appear on each package of Hair dyes. ''This preparation may cause serious inflammation of the skin in some cases & so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap & water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area & allow it to dry. After twenty four hours, wash the area gently with soap & water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each & every application. This preparation should on no account be used for dyeing eyebrows or eye-lashes as severe inflammation of the eye or even blindness may result.'' **ii) Vaccines-** **Labelling Provisions of Vaccines:** **(a) The label on the on the container shall display:** (i) The name of vaccine (Proper name). (ii) the batch number or lot number (iii) The total number of doses in the container or contents in milliliters. (iv) Potency. (v) Expiry date. **(b) In addition to above information, the label on the package shall show:** (i) Proper name. (ii) Contents in Millilitres or doses. (iii) Batch number. (iv) The name and address manufacturer. (v) Manufacturing licence No. (vi) The date of manufacture & date of expiry. (vii) Storage conditions.	**1½ M**

3	**c)**	**Give procedure for price fixation or revision of Bulk drug under DPCO 1995.** Under the provisions of DPCO 1995 to achieve the objectives of this order, Government has power to fix maximum sale price and also to revise the prices of bulk drugs after obtaining necessary information from a manufacturer or importer. While fixing sale prices of such bulk drugs, the govt. shall take into consideration i) A post-tax return of 14% on net worth or ii) A return of 22% on capital employed or iii) For a new plant, a return of 12% based on long term marginal costing iv) In cases where the production is from basic stage, a post-tax return of 18% on net worth or 26% on capital employed, depending upon option for rates of return exercised by manufacturer. No person shall sell a bulk drug at a price exceeding the maximum sale price fixed as per provisions of this order plus local taxes if applicable. After commencement of this order, if any manufacturer commences production of any scheduled bulk drug, he has to furnish the details in form I & any additional information to the govt. within 15 days. After receipt of such information & making necessary enquiry as it deems fit, Govt. may fix the maximum sale price of bulk drug & notify in the official Gazette. Govt. may also fix or revise the price of any non scheduled bulk drug on public interest. Manufacturer or importer of such bulk drug shall not sale such non scheduled bulk drug at a price exceeding the price so fixed or revised	**3M**
3	**d)**	**Explain role of Pharmacist in Healthcare.** 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 and effective use of drugs. iii) Pharmacy occupies an important position in the health care system. So the pharmacist	**3 M**

should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product.

iv) Pharmacist is legally held responsible for the quality of product which ismanufactured and distributed.

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

vi) They provide link between Physician & Patient

vii)They are able to advice patients with minor illness viii)The profession of Pharmacy presently consist of

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

ix)Pharmacist has to play an important role in areas such as:

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

3 **e)** **Differentiate between Law and ethics.** **1M each, any3**

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.	
3	**f)**	**Define "Cannabis" and "Opium Derivative" under NDPS acr, 1985.** **Cannabis (hemp)** means- i)Charas, which is a resin in crude or purified form obtained from the cannabis plant which includes concentrated preparation & resin known as hashish oil or liquid hashish. ii)Ganja, which comprises of flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops. iii)Any mixture with or without any neutral material of ganja or charas or any drink prepared from them. **Opium Derivative:** It includes i) Medicinal opium. ii) Prepared opium. iii) Phenanthrene alkaloids such as morphine, codeine, thebaine & their salts. iv) Diacetyl morphine (heroin) & its salts. v) All preparations containing more than 0.2% of morphine or any amount of diacetyl morphine.				**1½ M** **1½M**

4		**Answer any FOUR of the followings:**	**12M(3x4)**
4	**a)**	**How Diploma in Pharmacy Institute in India are approved by central council.** **Application by institution/ authority to the Pharmacy Council of India (PCI):** An institution which conducts course of study or hold an examination for the pharmacist, has to apply to the PCI for approval of the course or examination. **Inspection:** i)PCI after receiving such application appoints the inspectors to visit the institution & confirm that whether the institution has the prescribed facilities as per the E R or not. ii) Inspectors may also attend any examination, to judge its standards without interfering with its conduct. iii)The inspector then report to the PCI on the facilities available in the institution & on the conduct & standard of the examinations held. **Approval:** i)On the reports of the inspectors if the PCI is satisfied that the course or examination under consideration is in conformity with ER, it may grant approval to it & ii)The said course of examination shall be considered as approved for qualifying for registration as pharmacist under the act. **Declaration:** Declaration of approval made by resolution is passed at a meeting of the PCI & published in the Official Gazette.	**3 M**
4	**b)**	**Define "Drug Inspector". Give his powers under D and C Act, 1940.** **Drug Inspector** means- i) In relation to Ayurvedic, Siddha or Unani drug, an person appointed by the Central or State Government under section 33-G; & ii) In relation to any other drug or cosmetic, a person appointed by the Central or State Government under section 21	**1 M**

		Powers of Drug Inspector Within the local limits for which the Inspector is appointed, he may: **i) Inspect -** Any premises wherein any drug or cosmetic is being manufactured. And also he may 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	**2M, any4**

		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.	
4	**c)**	**Give requirements of Bonded Laboratory.** Requirements of bonded laboratory -The bonded laboratory should have - 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. 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. 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.	**3 M**

4	**d)**	**Define "Poison" under Poisons Act, 1919 and give its classification.** **Poison-** Any substance specified as a poison in rule made or notification issued under this Act, is considered to be poison for the purpose of this Act. **Classification of Poisons:** The poison act (12 of 1919) in Maharashtra the rules has been framed as Maharashtra Poisons Rules, 1972 and these include a Schedule giving a list of poisons, Class A and Class B, covered by the Poison Act. Class A poisons generally are those which have medicinal use while Class B poisons do not have any medicinal use. **Class A/ 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, StropanthinTartar emetic, Tetraethyl lead. **Class B/ 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. Or **Classification of Poisons:** As per Dr. R. S. Naik professor of Forensic Medicine, M G Institute of Medical sciences, Wardha. No classification of poison is entirely satisfactory, as many poisons fall into more than one group, however the classification given below:- 1)Corrosive :- group consist of strong acids and strong alkalis like, hydrochloric acid, oxalic acids, carbolic acids, salicylic acid, caustic soda, caustic potash 2)Irritants:- chlorine, bromine, iodine, boron, arsenic, antimony, mercury, lead, copper, zinc, magazine. 3)Neurotics:- alcohol, ether, chloroform, barbiturates, organophosphorus compounds, 4) Cardiac:- digitalis, oleander, aconite, tobacco.	**1M -Def** **2M for any classification , any 2 e.g. from each**

		5)Asphyxiants;- irrespirable gases, such as coal gas, carbon monoxide, carbon dioxide, sewer gas and war gases. 6) Miscellaneous :- aspirin, phenacetin, paracetamol, quinine, chlorpromazine, meprobamate, reserpine, amphetamine, LSD, Peyote, mescaline.	
4	**e)**	**Discuss Pharmacist in relation to his trade.** **1) Price Structure** - i) Prices charged from customers should be fair and in keeping with the quality of drugs & medical preparations supplied. ii) The compounding & dispensing charges should be fair & without unduly taxing the purchaser. **2) Fair Trade Practices** - i) No attempt should be made to capture the business of a fellow pharmacist by cut-throat competition, i.e. by offering reduced price, prizes or gifts ii) Labels, trademarks, symbols and other signs of fellow pharmacist should not be copied. iii) Drugs or other ingredients required should always be purchased from reputable source. **3) Hawking of Drugs** - i) Hawking of drugs and medicinal should not be allowed. ii) Any attempt should not be made to collect the orders from door to door. iii) Self-servicing method in pharmacy or drug - stores should not be allowed as it may encourage self-medication which is undesirable & dangerous. **4) Advertising and Displays** - No display or advertisement on the premises, in the newspaper or elsewhere regarding the abilities & services provided the pharmacy. Pharmacist should not make such advertisement which contains- i) Misleading, or exaggerated statements or claims. ii) The word "Cure" in reference to an ailment or symptoms of ill-health.	**3M**

		iii) A guarantee of therapeutic efficacy. iv) An appeal to fear. v) An offer to refund money paid. vi) A prize, competition or similar scheme. vii) A reference to sexual weakness, premature ageing.	
4	**f)**	**Describe the labeling requirement of ophthalmic preparation under D and C Act, 1940.** **Ophthalmic Solutions and Suspensions** – The following additional particulars shall be shown on the label of container- i) The statement 'Use the solution within one month after opening the container'. ii) Name and concentration of the 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 & consult physician. ii) Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solutions". **Ophthalmic Ointments** i) Special instructions regarding storage wherever applicable. ii) A cautionary legend reading **Warning** - If irritation persists or increases discontinue the use and consult physicians.	**2M** **1M**
5		**Answer any FOUR of the followings:**	**12M(3x4)**
5	**a)**	**Define "Registered Pharmacist" and "Displaced person" under Pharmacy Act, 1948.** **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. **Displaced person:-**	**1½ M for Each def**

		Displaced person mean i) A person who on account of setting up of dominions of India and Pakistan or on account of civil disturbances or the fear of such disturbances in area now forming part of Pakistan has on or after 1st day of March 1947, left or been displaced from his place of residence in such area and who has since then been residing in India. ii) Any person who on account of civil disturbances or the fear of such disturbances in area now forming part of Bangladesh, has after 14th day of April, 1957 but before 25th day March 1971, left or has been displaced from his place of residence in such area and who has since then been residing in India.	
	b)	**Define "Networth" and "Free Reserve".** **Networth** -It means the paid-up share capital of a company plus free reserve, if any and surpluses excluding outside investment which are not readily available for operational activity **Free reserve-** means a reserve created by appropriation of profits, but does not include reserves provided for contingent liability, disputed claims, goodwill, revaluation and other similar reserves.	**1½ M for Each,**
	c)	**Give various particulars required to be mentioned in application for obtaining license for manufacture in bond.** Following are the particulars which should be submitted in the application for obtaining license to manufacture in bond. i) Name and address of applicant, place and site on which bonded lab is proposed to be built. ii) If the application be a firm, the name and address of all partners of firm. iii) If it be company, its registered the name and address, as well as name and address of directors, managers and managing agent should be specified, amount of capital proposed to be invested. iv) Number and full description of vats, stills and other permanent apparatus and machinery which applicant wishes to set up together with the maximum quantity of alcohol at any one time to remain in the form of finished and unfinished preparations &	**3 M any 6**

		maximum quantities by weight of opium, Indian hemp or other narcotic drugs or narcotics and their contents in finished preparations. v) The approximate date from which the applicant desires to commence the manufacture. Statement whether the laboratory will require a whole time excise officer or part time. vi) List of preparations stating percentage of alcohol contained & license held under D&C Act 1948. vii) Site and elevation plan of laboratory building and similar plans for the quarters of the excise officer together with relevant record.	
	d)	**Discuss objectionable advertisement under Drugs and Magic Remedies Act, 1954.** **1) Advertisement of drugs which may lead to its/their use for the treatment of certain diseases and disorders -** i) For procurement of miscarriage or prevention of conception in women; or ii) For the correction of menstrual disorders in women; or iii) For the maintenance or improvement of the power of human beings for sexual pleasure. Or iv) For diagnosis, cure, alleviation, treatment or prevention of any disease or disorder or condition specified in the schedule or in rules made under the Act. **2) Advertisement of Magic Remedies for treatment of certain diseases or disorders** No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims 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 are prohibited. iv) Ayurvedic remedies to cure liver disorders & memory enhancement. **4) Prohibition of advertisements of Magic Remedies for the treatment of certain diseases -**	**3M, any 3**

		Publication of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited	
	e)	**Which are different circumstances under which pregnancy can be terminated under MTP At, 1971?** **1) Consent:-** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except: i) When the pregnant woman is less than 18 yrs. of age or ii) The pregnant woman is lunatic. In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian. **2) Duration of pregnancies:** 1) A pregnancy may be terminated if it is not more than 12 weeks old & a medical practitioner is of the opinion that continuation of such pregnancyi) May involve a serious risk to the life of pregnant woman, & would result into serious injury to the physical or mental health of the pregnant woman, ii) The child to be born would be seriously handicapped due to physical or mental abnormalities. 2) A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old & not less than 2 RMPs are of the same opinion as above. 3) A pregnancy of any duration may be terminated by RMP when is of the opinion that such termination is immediately necessary to save the life of pregnant women. **3) Other cases:-** The pregnancy caused due to rape or due to failure of contraceptive device used by any married woman or her husband for the purpose of family planning.	**3M**
	f)	**Give the functions of Central Drug Laboratory.** 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	**3 M , any 6**

		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 (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 excersied 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.	
6		**Answer any FOUR of the followings**	**16M (4x4)**
6	**a)**	**What are Education Regulations? Mention various particular under it.** 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	**1 M** **Meaning** **3M** **Explanation**
6	**b)**	**What does Sch H and Sch X to the D and C rules prescribed? Give any two example of each.** **Schedule H-** Prescription drugs which are required to be sold by retail only on the prescription of a RMP.	**1M for Schedule**

		Examples- Abacavir,Abciximab, Acamprosate Calcium, Acebutolol Hydrochloride, Aclarubicin, Albendazole, Alclometasone Dipropionate, Actilyse, Acyclovir, Adenosine, Adrenocorticotrophic Hormone (Acth), Alendronate Sodium, Allopurinol, Alpha chymotrypsin, Alprazolam, Amlodipine, Analgin, Androgenic Anabolic, Oestrogenic & Progestational Substances, Antibiotics, , Bacampicillin, Baclofen, Balsalazide, Bambuterol, Barbituric Acid, Basiliximab, Benazepril Hydrochloride, Benidipine Hydrochloride, Benserazide Hydrochloride, Betahistine Dihydrochloride, Bethanidine Sulphate, Bezafibrate, Bicalutamide, Biclotymol, Bifonazole, Bimatoprost, Biperiden Hydrochloride, Biphenyl Acetic Acid, Bitoscanate, Bleomycin, Brimonidine Tartrate, Bromhexine Hydrochloride, , Cabergoline, Calcium Dobesilate, Candesartan, Capecitabine, Captopril, Carbidopa, Carbocisteine, Carboplatin, Carboquone, Carisoprodol, L-Carnitine, Carteolol Hydrochloride, Cefazolin Sodium, Cefuroxime, Celecoxib, Centchroman, Centbutindole, Centpropazine, Cetirizine Hydrochloride, Vinblastine Sulphate, Vindesine Sulphate, Vinorelbine Tartrate, Xipamide, Zidovudine Hydrochloride, Ziprasidone Hydrochloride, Zoledronic Acid, Zolpidem, Zopiclone, Zuclopenthixol, Trapidil, Tegaserod Maleate, Teicoplanin, Telmisartan, Temozolamide, Terazosin, Terbutaline Sulphate, Terfenadine, etc**. (Any other e.g. specified under schedule H to be considered)** **Schedule X-** List of habit forming, psychotropic and other such drugs. **Examples**:- Amobarbital, Ethclorvynol , Phencycidine ,Amphetamine, Phenometrazine Barbital, Glutethimide, Cyclobarbital,Secobarbital ,Meprobamate, Methamphetamine Penobarbital, Methaqualone, Pentobarbital, Dexamphetamine ,Methylphenidate	**& 1M for e.g. any 2** **1M for Schedule & 1M for e.g. any 2**

6	**c)**	**Give offences and penalties under DMR Act, 1954.** Offences & Penalties under Drugs & Magic Remedies (O.A.) Act,1954 **Offence- 1)** Contravention of any of the provision of this Act or Rules- **Penalties:** Imprisonment 6 month or with fine or with both on 1st conviction. Imprisonment 1 year or with fine or with both on subsequent conviction **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.	**2 M** **2M**
6	**d)**	**Define "R.M.P" under MTP Act 1971. Explain various training and experiences for him under the act.** **Registered Medical Practitioner-** A medical practitioner who possesses any recognized medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 whose name has been entered in a State Medical Register & who has such experience or training in gynecology & obstetrics as the case may be prescribed by rules under this Act. **Experience or training :-** For the purpose of the act, the RMP should possess one or more of the following experience or training in gynecology and obstetrics – a)If he was registered in a state medical register immediately before the commencement of the act, experience in the practice of gynaecology and obstetrics for not less three years. b)A medical practitioner, registered in a state Medical Register on or after the date of commencement , can terminate the pregnancy.	**2 M for def.** **2M Explanation**

		i)If he has completed six months of house surgency in gynaecology and obstetrics; or ii)If he has experience at any hospital for not less than one year in the practice of gynaecology and obstetrics; or iii)If he has assisted a RMP in the performance of twenty five cases of medical termination of pregnancy in a hospital established or maintained , or a training institute approved by the Government, for this purpose. c)In the case of medical practitioner who has been registered in a state medical register and who holds a post graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of degree or diploma is considered.	
6	**e)**	**Explain various ethics to be followed by a person while dealing with the prescription.** i) Prescriptions should not be discussed with patients or others regarding the merits and demerits of their therapeutic efficiency. ii) After receiving the prescriptions, a pharmacist should not even show any expression on his face so that the patients will lose their faith in the physicians or prescribers. iii) No addition, omission or substitution of ingredients in a prescription should be made without the consent of prescriber or physician whenever possible except in an emergency. iv) In case of any error in the prescription, it should be referred back to the prescriber for necessary correction. v) If at all change in prescription is necessary in the interest of the health of the patient, it should not affect the reputation of the physician. vi) A pharmacist should not recommend any particular prescriber unless he is specially asked to do so.	**4 M**
6	**f)**	**Give penalties for various offences and under NDPS Act, 1985.** Offences and penalties are- **1. Punishment for contravention in relation to poppy straw**. -Whoever, in	**1 M for each, Any**

		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,- (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 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.	**4**

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 transhipment 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 transhipsany 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 ti 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.-(l) 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 27Aand 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.-(l) 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.-(l) 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.	