MODEL ANSWER

SUMMER – 17 EXAMINATION

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

Subject- Pharmaceutical Jurisprudence Subject Code: 0814

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any EIGHT of the following: (Each question carries 2 marks)**	**16M (2M X8)**
	a)	**Define "Law" and state importance of pharmaceutical law.** **Law-** Rules of human conduct binding on all persons in a state or nation. **Importance of Pharmaceutical Law-** i)) Pharmaceutical law covers the legal aspect relating to manufacture of drugs in Pharmaceutical industries, their storage, sale, distribution. ii) It helps the pharmacist to understand their legal & ethical responsibilities & their by avoid the danger of unnecessary legal proceedings. iii) The Pharmaceutical Law safeguards the health of the people by making right medication by controlling pharmacy business & profession. iv) The patient should get the drugs of good quality which are tested & evaluated for safety purpose. v) Pharmaceutical Laws relate to the creation, sale, distribution, and use of pharmaceutical drugs. vi) Another important role in product safety & marketing vii) To promote health care by regulating the manufacture, supply & distribution of good quality drugs. viii) To safeguard the people from misleading & false advertisements relating to drugs & remedies	1M Def. 1M Importance (any2)
	b)	**Give the objective of Pharmacy Act, 1948.** The main objective of Pharmacy Act is to regulate the profession and practice of pharmacy and to raise the status of profession of pharmacy in India	2M
	c)	**Define "Magic Remedy" as per the Drugs & Magic Remedies (O.A.) Act, 1954.** **Magic Remedies**: It includes a Talisman, Mantra, Kavacha, and any other charm claiming to possess miraculous powers. i) for diagnosis, treatment and prevention of any disease in human beings or animals, or ii)for affecting or altering the structure or organic function of the body of human being or animal.	2M

Q. No.	Sub Q. N.	Answers	Marking Scheme
	d)	**What are the objectives of Narcotic Drugs and Psychotropic Substances Act, 1985?** **The main object of this Act is-** i) To consolidate & amend law relating to Narcotic Drugs, ii) To make strict provision to prohibit, control & regulate the operations relating to Narcotic Drugs & Psychotropic Substances iii) To provide for matters connected therewith.	2M
	e)	**Define 'Toilet Preparation' as per the Medicinal and Toilet Preparations Act, 1955.** **Toilet Preparation-** The preparation intended to be used in the toilet of human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes..	2M
	f)	**Give two poisons from each List A and List B of the Poisons Act, 1919.** **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. **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.	1M any 2 List A 1M any 2 List B
	g)	**Define "Minor" and "Lunatic" as per the MTP Act, 1971.** **Minor-** Means a person who, under the provisions of the Indian Majority Act, 1875 is to be deemed not to have attained his majority. **Lunatic-** Has the meaning assigned to it in Section 3 of the Indian Lunacy Act, 1912.	1 mark for each definition

Q. No.	Sub Q. N.	Answer	Marking Scheme
	h)	**Define "cosmetic" as per D and C Act 1940.** Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or applied to any part of the human body for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as a component of cosmetic.	2M
	i)	**What schedule "G" and "M" specify as per The Drugs and Cosmetic Rules 1945** **Schedule G**:-List of substances required to be taken only under the supervision of a Registered Medical Practitioner. OR It is dangerous to take this preparations except under supervision of a Registered Medical Practitioner. **Schedule M -** Good manufacturing practices & requirements of factory premises, plant, equipment etc. for manufacture of drugs.	1mark for each schedule
	j)	**Give objectives of DPCO 1995** **Objectives of DPCO 1995:** i) To achieve adequate production. ii) To secure or regulate the equitable distribution. iii) To maintain and increase the supplies of bulk drugs and formulations and iv) To make these available at fair prices.	2M
	k)	**Name the committee formed in 1930 to study problems related to Drugs in India. Who was the chairman of the committee** 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.	2M

Q. No.	Sub Q. N.	Answer	Marking Scheme
	l)	**Give objective of DMR (O.A.) Act,1954** The Drugs and Magic Remedies Act passed with following main object: i) To control certain types of advertisement related to drugs. ii) To prohibit certain kinds of advertisements relating to magic remedies; which falsely claim and mislead the public, and iii) To provide for matters related therewith.	2M
2		**Answer any FOUR of the following:**	**(3M X 4)**
		What is Inter State Agreement? Give the composition of the State Pharmacy Council?	
	a)	**Inter State Agreement:** Where two or more states enter into an agreement, whereby the State Pharmacy Council of one of the state serves the needs of other state or states that agreement is called as Inter State Agreement. The states while entering into an agreement whereby Joint Pharmacy Councils are constituted, one state serves the need of the state. The states also determines about the exercising of various functions & which states will perform functions. **Composition of State Pharmacy Council:** **1)Elected members:** a) Six members, elected amongst themselves by Registered pharmacists of state. b) One member elected by the members of Medical Council of the State amongst themselves. **2)Nominated members**: a) Five members nominated by the State Government of whom at least three shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or be a registered pharmacists. **3)Ex-officio members:** a) Chief administrative medical officer of the State. b) The officer in charge of the drug control organization of the state; appointed under D. & C. Act, 1940. c) Government Analyst appointed under Drugs and Cosmetics Act, 1940. If there are more than one such Analyst, one may be nominated by the Government.	Inter - state agreement 1M Composition 2M

Q. No.	Sub Q. N.	Answer	Marking Scheme
	b)	**Give the qualification of First Register and state who maintains central registers.** **Qualification for entry in First Register**: A person who has attained age of 18 years, entitled to have his name in first register on payment of prescribed fees & should have the following qualification:- (i) A degree or diploma in pharmacy, or pharmaceutical chemistry, or chemist or druggist diploma of an Indian University or a State Government or prescribed qualification granted by an authority outside India, or (ii) A degree of an Indian University other than a degree in Pharmacy or Pharmaceutical chemistry & has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on the prescription of RMP for total period of not less than 3 years, OR (iii) Has passed an examination recognized as adequate by the State Govt. for compounders & dispensers. (iv) Has not less than 5 years experience of compounding & dispensing in a hospital or dispensary or other place in which drugs are regularly dispensed on the prescription of RMP. **Central Register**: Central Council maintains central registers.	Qualification-2M 1 Mark
	c)	**Discuss any three offences and penalties under Pharmacy Act, 1948.** 1) **Falsely claiming to be Registered Pharmacist**: <u>Penalties</u>: 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	1Mark for each, any 3

Q. No.	Sub Q. N.	Answer	Marking Scheme
		On first conviction, and with imprisonment up to 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', and '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**: Penalties: The persons other than registered pharmacist dispensing any medicine for patients is liable for punishment with imprisonment up to six months or with fine up to one thousand rupees or with both. 3) **Failure to surrender certificate of registration**: Penalties: Is also punishable with fine up to fifty rupees. 4) **Obstructing State Pharmacy Council Inspectors:** Penalties**:** Shall be deemed guilty of an offence & may be punished with imprisonment up to six month or fine up to 1000 Rs or both.	
	d)	**Which categories of the advertisement are prohibited to be made as per Drugs and Magic Remedies (O.A.) Act, 1954.** Classes of prohibited advertisements under Drugs & Magic Remedies Act and Rules: **1)** Advertisement of drugs which may lead to its/their use for the treatment of certain diseases and disorders: i) For procurement of miscarriage or prevention of conception in women; or ii) For the correction of menstrual disorders in women; or iii) For the maintenance or improvement of the power of human beings for sexual pleasure or iv) For diagnosis, cure, alleviation, treatment or prevention of any disease or disorder or condition specified in the schedule or in rules made under the act. **2)** Advertisement of Magic Remedies for treatment of certain diseases or disorders which may claim to be efficacious for any of the purposes specified in I as above.	1Mark for each, any3

Q. No.	Sub Q. N.	Answer	Marking Scheme
		3) Misleading advertisements in relation to drugs**,** which: i) Directly or indirectly gives false impression regarding true character of drug or drugs; or ii) Make any false claims for such drug or drugs iii) Is otherwise false or misleading in any material particularly. iv) Ayurvedic remedies to cure liver disorders & memory enhancement. **4)** Prohibition of advertisements of Magic Remedies for the treatment of certain diseases. Prohibition of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited	
	e)	**Define: (1) Opium and (2) Cannabis as per NDPS Act 1985.** **(1) 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)	1M
		(2) Cannabis: It includes the following: (i) Charas, which is a resin in crude or purified form obtained from the cannabis plant which includes concentrated preparations and resin known as hashish oil or liquid hashish. (ii) Ganja, which comprises of flowering or fruiting tops of the cannabis plant (excluding seeds and leaves not accompanied by the tops) (iii) Any mixture with or without any neutral material of ganja or charas or any drink prepared from them.	2M

Q. No.	Sub Q. N.	Answer	Marking Scheme
	f)	**Discuss any three offences and penalties under NDPS Act,1985** **Offences and penalties** **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,- **(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.	1 Mark each, any3

Q. No.	Sub Q. N.	Answer	Marking Scheme
		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.	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		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,	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		(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;	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		(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 tranships any narcotic drug or psychotropic substance shall be punishable,-	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		(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.]	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		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) willfully 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	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		(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	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		(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.	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		(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 under[39][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.	

<table>
<tr><th>Q. No.</th><th>Sub Q. N.</th><th>Answer</th><th>Marking Scheme</th></tr>
<tr><td>3</td><td>a)</td><td>
Attempt any FOUR of the following:
What is manufacture in Bond? Give two points to differentiate it from manufacture outside Bond as per Medicinal & Toilet prep. (ED) Act.
Manufacture in Bond:- 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.
Differentiation:-
<table>
<tr><th>Sr. No</th><th>Manufacture in Bond</th><th>Manufacture outside Bond</th></tr>
<tr><td>1</td><td>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.</td><td>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.</td></tr>
<tr><td>2</td><td>Alcohol on which duty has not been paid shall be used under the excise supervision</td><td>Only the alcohol on which duty has already been paid shall be used</td></tr>
<tr><td>3</td><td>License required should be obtained from Excise Commissioner</td><td>License required should be obtained from the officer as the State Government may authorize on this behalf</td></tr>
<tr><td>4</td><td>Preparations are deemed to be manufactured in bond when they are manufactured in premises licensed for this purpose.</td><td>Preparations are deemed to be manufactured outside bond when they are manufactured in premises licensed for this purpose.</td></tr>
</table>
</td><td>(3M X4)
1M
1Mark each, (any2)</td></tr>
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5	Suitable for large scale manufacture	Suitable for small scale manufacture

b) **State six rules made by the state govt. to regulate the permission and possession for sale of the specified poisons as per 'Poisons Act' 1919.** ½ mark each, any6

Possession for sale & sale of any Poison-

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.

The State Govt. has power to make such rules in this connection which may provide for -

i) 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.

ii) The classes of persons to whom the licenses for possession and possession for sale are be granted.

iii) The classes of persons to whom such poison may be sold.

iv) The maximum quantity of any poison that may be sold to a person.

v) The maintenance of the registers for sale of poisons and inspection of the same.

vi) Safe custody of poisons and the labelling of the vessels, packages or coverings in which such poison is sold or stored for sale.

vii) Inspection & examination of any such poison possessed for sale by any vendor.

viii)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.

	c)	**Give three examples each of Narcotic Drugs and Psychotropic Sub. As per NDPS Act 1985.** **Narcotic Drugs:-** 1.Coca Leaf, 2.Cannabis (Hemp), 3. (a) Acetorphine b) Diacetylmorphine(Heroin) c) Dihydrodesoxymorphine (Desomorphine) d) Etrophine e) Ketobemidone and their salts, preparations, admixtures, extracts and other substances containing any of these drugs. **Psychotropic Substances :** LYSERGIDE, ETICYCLIDINE, ROLICYCLIDINE, PSILOCYBINE, TENOCYCLIDINE, TETRAIIYDROCANNA, AMPHETAMINE, DEXAMPHETAMINE, MECLOQUALONE, METHAMPHETAMINE , MECLOQUALONE, METHAQUALONE, ALPRAZOLAM, AMFEPRAMONE, BENZPHETAMINE, BROMAZEPAM, CAMAZEPAM, CLOBAZAM, CLONAZEPAM, CLORAZEATE, CLOTIAZEPAM, CEORAZEPAM, DETAZOMA, ETHINAMATE, EHTYLLOFLAZEPAT, FLUDIAZPAM, FLUNITRAZEPAM, HALAZEPAM, HALOXAZOLAM , KETAZOLAM, LEFETAMINE, LOPRAZOLAM, LORMETAZEPAM, MAZINDOL, LORMETAZEPAM, MAZINDOL, MESAZEPAM MEHTYPRYLON,NIMETAZEPAM,OXAZOLAM,SECOBARBITAL AMOBARBITAL,CYCLOBARBITAL, PENTABARBITAL, PHENDIMETRAZINE, HENTERMINE, PINAZEPAM, PIPARADROL, PRAZEPAM, TEMAZEPAM, TETRAZEPAM, TRIZOLAM. etc. (any other e.g. mentioned under N.D.&P.S. Act,1985)	½ mark each, any3 ½ mark each, any3
	d)	**Define "Adulterated Drug" as per the Drugs and Cosmetics Act 1940.** A drug shall deemed to be adulterated- i) If it consists, in whole or in part, of any filthy, putrid or decomposed substance, or, ii) If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health, or, iii) If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or iv) If it bears or contains, a colour other than prescribed which may be used for the purpose of colouring only; or 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 Marks

	e)	**State six categories of drugs which are prohibited to be imported into India as per D&C Act 1940.** **Classes of drugs prohibited to import under D & C Act -** No person shall import: 1) Any drug which is not of a standard quality. (For this purpose standard quality means standard specified in second schedule of the Act). 2) Any misbranded drug. 3) Any adulterated or spurious drug. 4) Any patent or proprietary medicine, the true formula or list of active ingredients with their quantities, is not displayed in the prescribed manner on the label or container thereof. 5) Any drug which by means of any statement, design or device or by other means purports or claims to cure or mitigate any such disease or aliment as specified in schedule J or the Rules. 6) Any drug the import of which is prohibited by rules. 7) Any drug for which license is prescribed for its import, but not imported in accordance with such license. 8) Any drug in contravention to any provisions of the Act & Rules thereunder.	½ mark each, any6
	f)	**Give the provision applicable to sale of sch. X Drug as per D & C Act 1940 & Rule 1945.** Ans. Provision applicable to sale of schedule X drugs:- 1. Schedule X drugs shall be supplied only on a prescription of a RMP and such prescription should be in duplicate, one copy of which is retained by licensee and preserved for at least 2 years. Unless otherwise stated in the prescription by the prescriber, such drugs must not be dispensed more than once. 2. The supply of drugs specified in schedule X shall be recorded at the time of supply in a bound and serially page numbered register, specially maintained for the purpose and	3 Marks

		separate pages shall be allotted for each drug and the following particulars shall be entered in the register. i) Date of supply and opening and closing stocks of drug on that day and relevant bill numbers. ii) Name of drug, its manufacturer's name and Batch number or lot number. iii) Name and address of the purchaser/patient. iv) Date of prescription and name and address of RMP v) Signature of the registered pharmacist under whose supervision supply is made. 3. Transaction of schedule X drug should be recorded in separate register in which in addition to the above details, the quantities purchased should be recorded together with name and address of supplier and his license number. 4. Record of supply of schedule X drugs to Registered Medical Practitioners, hospitals, infirmaries or other institutions, should be preserved at least for 3 years from the date of supply. 5. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and rules and thereunder. 6. No drug shall be sold unless such drug is purchased under cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.	
4		**Attempt any FOUR of the following:**	**12Marks (3M X 4)**
	a)	**Give the list of licenses granted by the licensing authority for the sale of drugs as per D & C Act 1940.** <u>Different types of license required for the sale of drugs are given hereunder:-</u> 1) License on Form 20 is issued for the sale of Allopathic drugs by retail other than those specified in Schedule C, C(1) and X. 2) License on Form 20-A is issued for the sale of restricted Allopathic drugs by retail other than those specified in schedule C, C(1) and X. 3) License on Form 20-B is issued for wholesale of Allopathic drugs other than those specified in Schedule C, C(1) and X. 4) License on form 20-C is issued for sale of Homoeopathic medicines by retail.	½ mark each, any6

		5) License on Form 20-D is issued for sale of Homoeopathic Medicines by wholesale. 6) License on Form 21 is issued for retail sale of Allopathic drugs specified in Schedule C & C(1). 7) License on Form 21-B is issued for wholesale of Allopathic drugs specified in Schedule C &C(1). 8) License on form 21-A is issued for retail sale of restricted Allopathic drugs specified in Schedule C & C(1) 9) License on Form 20-F is issued for retail sale of drugs specified in Schedule 'X'. 10) License on Form 20-G is issued for wholesale of drugs Specified in Schedule 'X	
	b)	**What is repacking of drugs? Give five conditions of Repacking License as per D & C Act 1940.** **Repacking of drugs**- It is the process of breaking up any drug from a bulk container into small packages and the labeling of each such package with a view to its sale and distribution. But, it does not include the compounding, dispensing or the packing of any drug in the ordinary course of retail business. **Conditions of repacking** Persons licensed to repack drugs should observe the following conditions- 1) Adequate space & equipment for the repacking operations which must be carried out under hygienic conditions & under supervision of Competent Person. 2) License should maintain adequate arrangement for analysis and testing of each batch of raw material and repacked drugs or by testing approved institutions, maintain record for the period of 3 years from date manufacturing and in case of drugs with expiry date at least for 3 months from such date. 3) The drugs repacked should, in addition to other particulars, bears the no. of license preceded by the words 'Rpg. Lic. No.' on their label. 4) Application for the grant or renewal of such license shall be made in Form 24-B & the license shall be issued in Form 25-B. 5) License required for the repacking of drugs other than those specified in schedule C and C1. 6) The factory premises should comply with requirement specified as per schedule M, the licenses should make adequate arrangement for the storage of drugs 7) Licensee shall allow Inspector to inspect records and registers maintained under these	½ mark ½ mark each, any5

		rules. Also allow any Inspector to enter with or without notice, in any premises, where packing of drugs is carried on and to inspect premises & to take samples of repacked drugs. 8) The licensee shall maintain an Inspection book in Form 35 to enable Inspector to record his impression and the defects noticed. 9) Any change in the competent staff named in the license should be forthwith notified to the licensing authority. 10) The license should comply with the provision of the Act and the Rules and with such further requirement of which he has been not less than 4 months' notice by the licensing authority.	
	c)	**What special details are required to be mentioned on the label of "Ophthalmic Preparations "as per Drugs and Cosmetics Rule 1945.** **Ophthalmic preparations** **<u>Ophthalmic solutions and suspensions</u> :** the following additional particular 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 and consult physician. ii) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate solution. **<u>Ophthalmic ointments</u> :** i)Special instructions regarding storage wherever applicable. ii)WARNING : If irritation persists or increases, discontinue the use and consult physician.	2Marks 1 mark

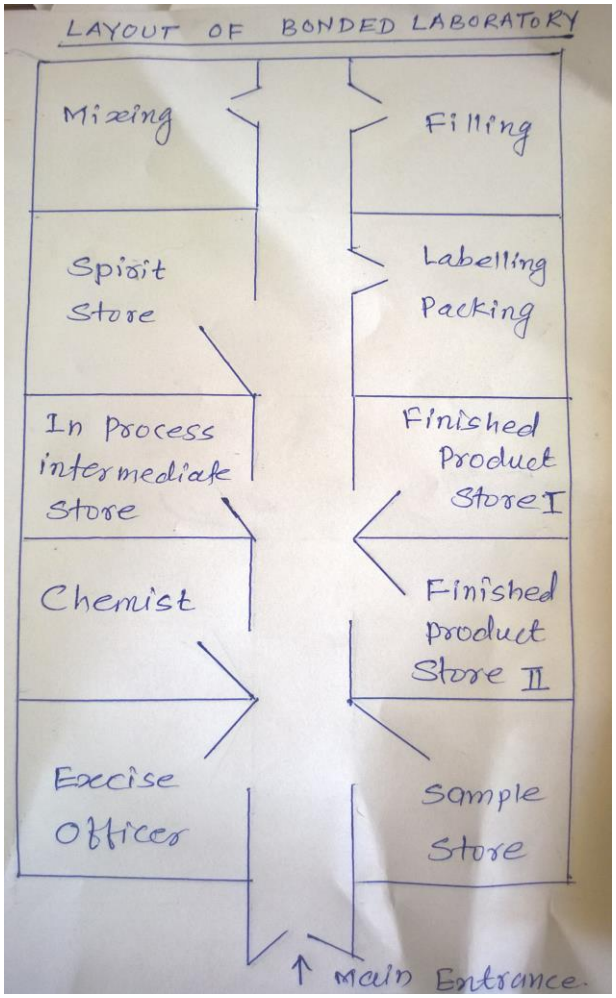
	d)	**Give the bonafide reasons for termination of pregnancy under medical termination of pregnancy Act, 1971.** **1) Consent:-** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except: i) When the pregnant woman is less than 18 yrs. of age or ii) The pregnant woman 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 pregnancy i) May involve a serious risk to the life of pregnant woman, & would result into serious injury to the physical or mental health of the pregnant woman, ii)The child to be born would be seriously handicapped due to physical or mental abnormalities. 2) A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old & not less than 2 RMPs are of the same opinion as above. 3) A pregnancy of any duration may be terminated by RMP when is of the opinion that such termination is immediately necessary to save the life of pregnant women. **3) Other cases:-** The pregnancy caused due to rape or due to failure of contraceptive device used by any married woman or her husband for the purpose of family planning.	3marks
	e)	**Discuss the ethics of pharmacist in relation to his trade as per the code of Pharm.** **Ethics.** **A] Price Structure:** Prices of drugs & medicinal preparations charged from the customers should be fair & including dispensing & compounding charges without unduly taxing the purchaser. **B] Fair Trade practice-**	3Marks

		i) A pharmacist should not make any attempt to capture the business of fellow pharmacist by unhealthy competition or cut-throat competitions, that is by offering reduced price, gifts, prizes etc. ii) Trademarks, labels, symbols or any other signs of other pharmacists should not be copied or imitated. iii) Drugs or other ingredients required should always be purchased from reputable sources. **C] Hawking of drugs & other-** i) Hawking of drugs & medicines should not be practiced & any attempt should not be made to collect the orders from door to door. ii)Self servicing method in the pharmacy or drug stores should not be allowed as it would encourage self-medication which is undesirable & dangerous **D] Advertisement & display-** There should not be any display or advertisement on the premises, in the newspaper or elsewhere regarding the abilities & services provided by the pharmacy. The pharmacist should not make such advertisements which contains: - i) Misleading or exaggerated statements or claims. 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 ailment or symptoms of ill-health	
	f)	**Define :- i)Restricted preparation** **ii)Unrestricted preparations under M.T.P. (E.D.) Act, 1955.** **i) Restricted preparation:-** These are the medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages. **ii) Unrestricted preparation:-** These are medicinal preparations which are considered to be not capable of being, misused as ordinary alcoholic beverages.	1 ½ marks for each

5		**Answer any FOUR of the following**	**12Marks (3M X 4)**
	a)	**How the retail price of a formulation is calculated as per the Drugs (Price Control) Order?** The retail price of a formulation shall be calculated by the Government in accordance with the following formula- **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 and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf; **C.C.**- means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; **P.M.**- means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf; **P.C.**- means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; **MAPE**- (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations; **E.D.**- means excise duty: In the 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 importer's profit is also taken into account. Landed cost means the cost of import of formulation inclusive of customs duty and clearing charges.	Formula- 1M Explanation 2M

	b)	**Give the provisions applicable for the sale of split quantities of drugs as per & C Act and Drugs (P. L.) Order.** No dealer shall sell loose quantity of any formulation drawn from a pack of such formulation at a price which exceeds the pro-rate (retail) price of formulation plus 5% thereof, provided such formulations shall not be compounded at the premises of the dealer.	3 marks
	c)	**How the (1) Expired Drugs and (2) Vet. Medicines stored in the Medical stores as per D & C Act & rules.** **(1)Storage of Expired Drugs –** In medical store, there should be separate arrangement for storage of expired drugs. The expired drugs should be stored in a separate cupboard or drawer or compartment. The top of the packages or cartons display prominently the words "Not for Sale". On that cupboard there should be label indicating 'Expired Drugs' written in a conspicuous manner. That compartment should separate from other medicine. The pharmacist in charge should take care to separate expired drugs from other medicines. **(2) Storage of Veterinary Medicines -** The medicines for treatment of animals kept in a retail shop or premises shall be labeled with the words 'Not for human use - for treatment of animals only' and shall be stored- i) In a cupboard or drawer reserved solely for the storage of veterinary drugs, or ii) In a part of the premises separated from the remainder of the premises to which customers are not permitted to have access.	1 ½ marks 1 ½ marks

	d)	**Give the layout and minimum requirements of a bonded laboratory as per M & T (E. D.) Act 1955.**	Layout- 1M



<u>Requirements of bonded laboratory</u>:

1) A Spirit store.
2) Separate room/ rooms for the manufacture of medicinal preparations and toilet preparations.
3) Separate room/ rooms for storage of the finished medicinal preparations and finished toilet preparations.
4) Accommodation near the entrance for the officer-in-charge with necessary furniture.
5) The pipes from sinks or wash-basins should be connected with general drainage of the

2 marks

		laboratory. 6) The gas and electric connection supply should be such that their supply can be cut-off at the end of day's work. 7) Every room should bear a board indicating the name of room and serial numbers. 8) Every window would be provided with specific arrangements of malleable iron rods of prescribed dimensions and window should be covered on the inside with strong wire netting of mesh not exceeding 25mm. 9) There shall be only one entrance to the laboratory and one door to each of its compartments. All the doors shall be secured with excise ticket locks in the absence of officer in-charge. 10) All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial numbers and full capacity. 11) The vessels for storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks	
	e)	**Give the constitution, Composition and function of Narcotic Drugs and Psychotropic substances consultative committee as per NDPS Act.1985** The Central Government by notification in the Official Gazette constitute an advisory committee known as -"The Narcotic Drugs and Psychotropic Substances Consultative Committee" Constitution - The Committee consist of a Chairman and such other members not exceeding 20, as may be appointed by the Central Government. For efficient discharge of its functions the committee may constitute and appoint one or more sub-committees. <u>Function</u> - To advise the Central Government on the matters relating to the administration of this Act.	2M Constitution & composition 1M function

	f)	**Explain:(1) Handling of prescription and** **(2)Clan – destine arrangement as per code of Pharmaceutical ethics.** **(1) Handling of prescription** i) Prescription presented for dispensing should not discussed with patients or others regarding the merits and demerits of their therapeutic efficiency. ii) After receiving the prescriptions, a pharmacist should not show any facial expression so that the patients will lose their faith in the physicians or prescribers. iii) No addition, omission, or substitution of any ingredients in a prescription should be made without consent of prescriber except in an emergency. iv) In case of any obvious error in the prescription, it should be referred back to the prescriber for correction or approval of the change suggested. v) If at all the change in the prescription is necessary in the interest of the health of patient, it should not affect the reputation of the physician or prescriber. vi) A pharmacist should not recommend any particular prescriber, unless he is specially asked to do so. **(2)Clan –destine arrangement as per code of Pharmaceutical ethics.** No pharmacist should enter into any secret agreements or contract with a physician, medical profession, dentist, veterinary surgeons to offer them any commission or gifts by recommending his dispensary or drug store.	2marks 1 mark
6		**Answer any FOUR of the following**	**16Marks**
	a)	**Enlist the Ex-officio members of DTAB as per D & C Act.** i) The Director General of Health Services, who is the Chairman of the board. ii) The Drugs Controller of India. iii) The Director of the Central Drugs Laboratory, Calcutta. iv) The Director of the Central Research Institute, Kasauli.	**(4M X 4)** 4 Marks

		v) The Director of Indian Veterinary Research Institute, Izatnagar. vi) The Director of Central Drug Research Institute, Lucknow. vii) The President of Medical Council of India. viii) The President of the Pharmacy Council of India.	
	b)	**Answer the following as per the Pharmacy Act, 1948** **(i) What are the duties of the PCI inspectors ?** **(ii) When the seat of a PCI member is deemed to be vacated ?**	
		(i)What are the duties of the PCI Inspectors ? An Inspector may- i) Inspect any institution which provides an approved course of study. ii) Attend at any approved examination. iii) Inspect any institution whose authorities have applied for the approval of its course of study or examination. iv) An Inspector attending at any examination without interferes with the conduct of the examination & report to the Executive Committee on the sufficiency of examination.	2 marks
		(ii)When the seat of a PCI member is deemed to be vacated? i)A nominated or elected member may resign his membership at any time by writing to President and the seat of such member shall become vacant. ii)A nominated or elected member should have to vacate his seat if he is absent without excuse, in the opinion of the Central Council, for three consecutive meetings of the Central Council. iii)A casual vacancy in the Central Council shall be filled by fresh nomination or election, as the case may be, and the person nominated or elected to fill the vacancy shall hold office only for the remainder of the term.	2marks
	c)	**Write in detail about Sch. 'N' of the D & C rules 1945.** Schedule N- List of minimum equipment for the efficient running of a pharmacy 1) **Entrance** - The front of a pharmacy shall bear an inscription "Pharmacy".	4 marks

2) **Premises** –

The premises of a pharmacy shall be separated from rooms for private use.

The premises shall be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock especially medicaments and poisons to be kept in a clearly visible and appropriate manner.

The area of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters.

The floor of the pharmacy shall be smooth and washable.

The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.

A pharmacy shall be provided with ample supply of good quality water.

The dispensing department shall be separated by a barrier to prevent the admission of the public.

3) **Furniture and apparatus** –

A pharmacy shall contain furniture of required size & suitable apparatus.

Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of contents of containers kept near them.

Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size, easily readable with names of medicaments as given in the Pharmacopoeias.

A pharmacy shall be provided with a dispensing bench having impervious & washable top.

A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the work 'POISON' in red letters on a white background.

Containers of all concentrated solution shall bear special label or marked with the words "To be diluted".

A Pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions-

Apparatus-

- Balance, dispensing, sensitivity 30 mg.
- Balance, counter, capacity 3 Kgm, sensitivity 1 gm.
- Beakers, lipped, assorted sizes, Bottles, prescription, ungraduated assorted sizes
- Cork, extractor, Evaporating dishes, porcelain, Filter paper, Funnels, glass, Litmus paper, blue and red, Measure glasses cylindrical 10 ml, 25 ml, 100 ml and 500 ml
- Mortars and pestles, glass, Ointment pots, Ointment slab, porcelain, Pipettes, graduated, 2 ml, 5 ml and 10 ml
- Rubber stamps and pad, Scissors, Spatulas, rubber or vulcanite, Spatulas, stainless steel.
- Spirit lamp, Glass stirring rods, Thermometer, $0^{o}C$ to $200^{o}C$, Tripod stand ,Watch glasses, Water bath, Pill Machine, Pill Boxes, Suppository mould.

Books:

i) The Indian Pharmacopoeia (current Edition)
ii) National Formulary of Indian (Current Edition)
iii) The drugs and Cosmetics Act, 1940
iv) The Drugs and Cosmetics Rules, 1945
v) The Pharmacy Act, 1948
vi) Narcotic Drugs and Psychotropic Substances Act,1985
vii) The Dangerous Drugs Act, 1930

4) **General provisions -**

A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises.

The Pharmacist shall always put on clean white overalls.

The premises and fittings of the pharmacy shall be properly kept and everything shall be in good order and clean.

All records and registers shall be maintained in accordance with the laws in force.

Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked.

The keys of the poison cupboard shall be kept in the personal custody of the responsible

		person. Medicaments when supplied shall have labels conforming to the provisions of the laws in force. **Note: -** The above requirements are subject to modifications at the discretion of the licensing authority. The decision of the licensing authority in that regard shall be final.	
	d)	**Give the procedure to be followed by a drugs Inspector while collecting samples from a manufacturing premises as per Drugs & cosmetic rules 1945.** Where an Inspector takes any sample of a drug or cosmetic, he shall - i) Intimate the purpose to a person from whom he takes sample in writing in the prescribed form (Form-17) ii) Tender fair price of the sample & obtain acknowledgement thereof. If price is refused, by such person, he has to tender a receipt thereof in the prescribed form (Form 17-A). iii) Divide the sample in the presence of such person in three portions unless he willfully absents himself, shall & effectively seal and mark the portions so sealed. Further if drug is packed in small volume containers or gets damaged or deteriorates on exposure, 3 or 4 containers to be taken as the case may be & sealed & marked. i) Restore one portion or container of a sample with the person from whom sample is taken. ii) Send one portion or container to the Government Analyst for test or analysis. iii) Reserve one portion or container for production before the Court if proceedings are instituted in case of such sample. iv) Send remaining portion to a warrantor, if any, (whose name, address and other particulars have been disclosed)	4marks

Q. No.	Sub Q. N.	Answer	Marking Scheme
	e)	**How drugs are imported for personal use as per D & C Act.** Small quantities of drugs, the import of which is otherwise prohibited under Section 10 of the Act, may be imported for personal use subject to the following conditions- i) The drugs shall form part of a passenger's bona fide baggage or luggage; ii) The drugs shall be declared to the Customs authorities if necessary; iii) The quantity of any single drug so imported shall not exceed 100 average doses. Provided that the licensing authority may in an exceptional case in any individual case sanction the import of a large quantity. Provided that any drug, imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions- i) The licensing authority, an application made to it in Form 12-A is satisfied that the drug is for bona fide personal use; ii) The quantity to be imported is reasonable in the opinion of the licensing authority& is covered by prescription from a registered medical practitioner ; & iii) The licensing authority grants a permit in respect of the said drug in Form 12-B.	4 marks
	f)	**Discuss in brief how pharmacist is an integral part of Health care system.** All the pharmacists working in different fields of profession are directly or indirectly related to nation's health. Community pharmacist and hospital pharmacists are health professionals for the safe & effective use of drugs. Pharmacy occupies an important position in the health care system. So the pharmacist should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product. Pharmacist is an expert on drugs. With the developing trend in science and technology as well as in the potent and synthetic drugs, pharmacists' responsibility is increased to give information to the physician and the	4 marks

patients regarding the use, side-effects, etc. of such drugs in the interest of public health.

Pharmacist is legally held responsible for the quality of product which is manufactures and distributed.

They supply medicines against prescriptions.

They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes.

They provide link between Physician & Patient

They are able to advice patients with minor illness

The profession of Pharmacy presently consists of -

i) Industrial pharmacist
ii) Hospital pharmacist
iii) Academic pharmacist
iv) Community pharmacist

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

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