



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.

Sillypharma.com

**MODEL ANSWER****WINTER- 19 EXAMINATION****Subject Title: Pharmaceutical Jurisprudence**

Subject Code:

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Q. No	Sub Q. N.	Answer	Marking Scheme
1		Answer any Eight of the followings:	16M
1	a)	Define 'Adulterated Drug'. 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.	2M (Any 2)
1	b)	Define law. What are the objectives of Pharmaceutical Legislation? Law- Rules of human conduct binding on all persons in a state or nation. Objectives- 1) To promote health care by regulating the manufacture, supply & distribution of good quality drugs. 2) To make these drugs available to the public at reasonable prices & through qualified person. 3) To safeguard the people from misleading & false advertisements relating to drugs & remedies 4) To regulate the profession of pharmacy. 5) To promote the Indigenous research technology.	1M Def. 1M Object. (Any 2)



1	c)	Define drug store and chemists as per D and C Act 1940. Drug Store: Licensed premises for the sale of drugs, which do not require the services of a qualified Person. Chemist and Druggist Licensed premises for the sale of drugs which require the services of a “Qualified Person” but where the drugs are not compounded against the prescriptions.	1M Each
1	d)	Write the functions of Narcotic commissioner of state. Functions:- i) Supervision of cultivation of opium poppy ii) Supervision of production of opium iii) Any other functions as may be performed to him by Government. <i>Sillypharma.com</i>	2M
1	e)	Define Poison. Write objective of Poison Act 1919. Definition:- Any substance specified as a poison in a rule made or notification issued Under the Poison Act, 1919 shall be deemed to be a poison for the purpose of this Act. Objective:- i) To regulate & control import, possession & sale of poisons. ii) According to the provision of Poison Act, 1919 Central Govt. has been authorized to regulate the import of poisons in India. & State Govt. has been authorized to make rules to regulate possession & sale of poison within their respective areas.	1M Def. 1M Object
1	f)	What are education regulations? 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	2M



		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.	
1	g)	Mention different sale licence required for retail and wholesale of schedule C and C₁ drugs. Retail sale: (i) For drugs those specified in schedule C and C ₁ : Form-21 Wholesale sale: (i) For drugs specified in schedule C and C ₁ : Form -21B	1M Each
1	h)	Define 'Dutiable goods', under medicinal and toilet preparations Act, 1955. Definition of Dutiable goods: It includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.	2M
1	i)	Enlist the objectives of drug and magic remedy Act ,1954(any two) 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, Any2
1	j)	Define under pharmacy Act 1948 'Registered Pharmacist'. 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.	2M

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1	k)	Give the objectives of drugs and price control order 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
1	l)	Mention ex-officio members of P.C.I. Ex-officio members of PCI: i)The Director General of Health Services. ii)The Drugs Controller of India. iii)The Director of the Central Drugs Laboratory.	2M
2		Attempt any FOUR of the followings	12M
2	a)	What are “Loan licenses” and “Restricted licenses” under D and C Act, 1940? (i) Loan licence: <i>Sillypharma.com</i> It means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee/ manufacturer. (i)Application for the grant or renewal of loan licences to manufacture for sale or for distribution of drugs other than those specified in Schedule C, Schedule C (1) & Sch. X shall be made up to ten items for each category of drugs shall be made in Form 24-A accompanied by a licence fee of rupees 6000/- & an inspection fee of rupees 1500/- to the licensing authority. (ii)The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, & facilities for testing, to undertake the manufacture on the behalf of the applicant for a loan licence (iii)Application for manufacture of more than ten items for each category of drug on a loan licence shall be accompanied by an addition fee of rupees 300/- per additional item specified in Schedule M.& M-III (iv)If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost	1 ½ M Each

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		<p>or otherwise rendered useless he may, on payment of a 1000/- Rs issue a duplicate licence.</p> <p>(v)An original licence or a renewed licence in Form 25 valid for a period of five years on which it is granted or renewed.</p> <p>(ii)Restricted licences :</p> <p>(i)Restricted licences shall be issued subject to the discretion of the Licensing Authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.</p> <p>(ii)Licences to itinerant vendors shall be issued only in exceptional circumstances for bonafide traveling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in rural areas where other channels of distribution of drugs are not available.</p> <p>(iii)For restricted licence, applicant has to make an application in Form-19A and the licence issued for drugs other than those specified in schedule C,C(1),and X in Form 20A and for drugs specified in schedule C, C(1) in Form 21-A</p> <p>The restricted licence in Form 21-A may also issued to a travelling agent of a firm for drugs specified in Schedule C.</p> <p>(iv)Such licence is not needed for vendors for the specific purpose of distribution to medical practioner or dealers.</p> <p>(v)Such licence in not needed to traveling agents of licensed manufacturers, agents of such manufacturers and importers of drugs engaged in free distribution of samples of medicine among members of the medical profession, hospitals, dispensaries and the medical or research institutions</p>	
2	b)	<p>State the particulars required to be mentioned on label of ophthalmic preparations under D and C Act, 1940.</p> <p>Ophthalmic Solutions and Suspensions –</p> <p>The following additional particulars shall be shown on the label of container</p> <p>i)The statement ‘Use the solution within one month after opening the container’.</p>	2M

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		<p>ii) Name and concentration of the preservative used.</p> <p>iii) The words ‘NOT FOR INJECTION’.</p> <p>iv) Special instructions regarding storage, wherever applicable.</p> <p>v) A cautionary legend reading as:</p> <p>WARNING</p> <p>i) If irritation persists or increases, discontinue the use & consult physician.</p> <p>ii) Do not touch the dropper tip or other dispensing tip to any surface since this may Contaminate solutions”.</p> <p>Ophthalmic Ointments</p> <p>i) Special instructions regarding storage wherever applicable.</p> <p>ii) A cautionary legend reading</p> <p>Warning - If irritation persists or increases discontinue the use and consult physicians.</p>	1M
2	c)	<p>Give the classes of advertisements which are prohibited under drug and magic remedies Act, 1954. <i>Sillypharma.com</i></p> <p>Classes of prohibited advertisements under Drugs & Magic Remedies Act and Rules:</p> <p>1) Advertisement of drugs which may lead to its/ their use for the treatment of certain diseases and disorders:</p> <p>i) For procurement of miscarriage or prevention of conception in women; or</p> <p>ii) For the correction of menstrual disorders in women; or</p> <p>iii) For the maintenance or improvement of the power of human beings for sexual pleasure or</p> <p>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.</p> <p>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.</p> <p>3) Misleading advertisements in relation to drugs, which:</p> <p>i) Directly or indirectly gives false impression regarding true character of drug or drugs; or</p>	3M



		<p>ii) Make any false claims for such drug or drugs</p> <p>iii) Is otherwise false or misleading in any material particularly.</p> <p>iv) Ayurvedic remedies to cure liver disorders & memory enhancement.</p> <p>4) Prohibition of advertisements of Magic Remedies for the treatment of certain diseases.</p> <p>Publication of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited.</p>	
2	d)	<p>What are the requirements of bonded manufactory or laboratory?</p> <p>Requirements of bonded manufactory</p> <p>1) A Spirit store, (if a distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory).</p> <p>2) Separate room/ rooms for the manufacture of medicinal preparations and toilet preparations.</p> <p>3) Separate room/ rooms for storage of the finished medicinal preparations and finished toilet preparations.</p> <p>4) Accommodation near the entrance for the officer-in-charge with necessary furniture.</p> <p>5) The pipes of sink or wash-basins should be connected with general drainage of the laboratory.</p> <p>6) The gas and electric connection supply should be such that their supply can be cut-off at the end of day's work.</p> <p>7) Every room should bear a board indicating the name of room and serial numbers.</p> <p>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.</p> <p>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.</p> <p>10) All vessels intended to hold alcohol and other liquid preparations should bear a</p>	3M

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		<p>distinctive serial numbers and full capacity.</p> <p>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.</p>	
2	e)	<p>Describe the offences and penalties under NDPS Act, 1985.</p> <p>Offences and penalties</p> <p>1. Punishment for contravention in relation to poppy straw. -Whoever, in contravention of any provisions of this Act or any rule or order made or condition of a license granted thereunder, produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw or removes or does any act in respect of warehoused poppy straw shall be punishable,-</p> <p>(a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees or with both;</p> <p>(b) where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years and with fine which may extend to one lakh rupees;</p> <p>(c) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees.</p> <p>Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupee</p> <p>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.</p> <p>3. Punishment for contravention in relation to prepared opium :-Whoever, in</p>	<p>1 ½ M</p> <p>Offences,</p> <p>any 3</p> <p>1 ½ M</p> <p>Penalties,</p> <p>any 3</p>

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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

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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; Exceeding two lakh rupees.

9.Punishment for illegal import in to India, export from India or transshipment of narcotic drugs and psychotropic substances.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license or permit granted

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or certificate or authorization issued thereunder, imports into India or exports from India or tranships any narcotic drug or psychotropic substance shall be punishable,-

(a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine, which may extend to ten thousand rupees or with both;

(b) where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment- for a term which may extend to ten years, and with fine; which may extend to one lakh rupees;

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

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

10. Punishment for external dealings in narcotic drugs and psychotropic substances

in contravention of section 12.-Whoever engages in or controls any trade whereby a narcotic drug or a psychotropic substance is obtained outside India and supplied to any person outside India without the previous authorization of the Central Government or otherwise than in accordance with the conditions (if any) of such authorization granted under section 12, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but may extend to two lakh rupees:

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

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

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

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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

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



15. Punishment for financing illicit traffic and harbouring offenders.-Whoever indulges in financing, directly or indirectly, any of the activities specified in sub-clauses (i) to (v) of clause (viii) of section 2 or harbours any person engaged in any of the aforementioned activities, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

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

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

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

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



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

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

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

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

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

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		<p>(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.]</p> <p>21-A-Death penalty for certain offences after previous conviction.-</p> <p>(1) Notwithstanding anything contained in section 31, if any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable 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-</p> <p>(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.]</p> <p>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.</p>	
2	f)	<p>Define:</p> <p>(i)Alcohol</p> <p>(ii)Medicinal opium</p> <p>(i)Alcohol: Alcohol means ethyl alcohol of any strength and purity having chemical composition C_2H_5OH.</p> <p>(ii)Medicinal opium: Opium which has undergone the processes necessary to adapt it for medicinal use in accordance with the requirements of the Indian Pharmacopoeia or any other Pharmacopoeia notified in this behalf by the Central Government, whether in powder form or granulated or otherwise or mixed with neutral materials;</p>	<p>1 ½ M</p> <p>Each</p>

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3		Attempt any FOUR of the followings	12M
3	a)	<p>Give constitution and function of DTAB.</p> <p>Ex-officio members.</p> <p>i) The Director General of Health Services, who is the Chairman of the board.</p> <p>ii) The Drugs Controller of India.</p> <p>iii) The Director of the Central Drugs Laboratory, Calcutta.</p> <p>iv) The Director of the Central Research Institute, Kasauli.</p> <p>v) The Director of Indian Veterinary Research Institute, Izatnagar.</p> <p>vi) The Director of Central Drug Research Institute, Lucknow.</p> <p>vii) The President of Medical Council of India.</p> <p>viii) The President of the Pharmacy Council of India.</p> <p>Nominated Members -Following members nominated by Central Government.</p> <p>i) Two persons from among persons who are in-charge of the drugs control in the states</p> <p>ii) One person from the pharmaceutical industry.</p> <p>iii) Two Government Analysts.</p> <p>Elected Members</p> <p>i) One teacher in Pharmacy, Pharmaceutical Chemistry or Pharmacognosy on the staff of an university or affiliated college elected by the Executive Committee of Pharmacy Council of India.</p> <p>ii) One teacher in medicine or therapeutics on the staff of an university or affiliated college elected by the Executive Committee of Medical Council of India.</p> <p>iii) One Pharmacologist, elected by the Governing Body of the Indian Council of Medical Research.</p> <p>iv) One person elected by the Central Council of Indian Medical Association.</p> <p>v) One person elected by the Council of the Indian Pharmaceutical Association.</p> <p>Functions of DTAB:</p> <p>i)To advice the Central Govt. & state Govt. On technical matters arising out of the administration of this Act.</p> <p>ii)To carry out the other functions assigned to it by this act.</p>	2M Constitut ion 1M function

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3	b)	<p>Define 'Drug' under D and C Act, 1940.</p> <p>Drugs : it includes</p> <ol style="list-style-type: none">1. All medicines for internal or external use of human beings or animals and all substances intended to be used for; or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.2. Such substances other than food intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in the human beings or animals.3. All substances intended for use as components of a drug including empty gelatin capsules and4. Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of diseases or disorders in human beings or animals. <p><i>Sillypharma.com</i></p>	3M
3	c)	<p>What does Schedule Y and Schedule H to the D and C rules prescribes?</p> <p>Schedule Y: Requirements and Guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials.</p> <p>Schedule H: Prescriptions drugs which are required to be sold by retail only on prescription of Registered Medical Practitioner.</p>	1 ½ M Each
3	d)	<p>As per as code of ethics explain, how pharmacist is a link between medical profession and public.</p> <p>A pharmacist under no circumstances, should practice medicine, that is diagnosing diseases and prescribing medicines. However in case of accidents or emergencies, he may render first aid services.</p> <p>A pharmacist should not recommend any particular medical practitioner, unless specially asked for. Pharmacist should never enter into secret agreements with the medical profession, physicians, dentist, and veterinary surgeons to offer them commission or gifts by recommending his dispensary or drug store. Pharmacist should not have any</p>	3M

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		<p>clandestine or underhand arrangement with any physician.</p> <p>Pharmacist is a link between medical profession and public. He should be constantly in touch with the modern developments in pharmacy and allied fields. He should be expert in the field of pharmacy so that he may advice the physician on pharmaceutical matters. By enlarging his store of knowledge he may be able to educate the public to maintain their health. Pharmacists should neither discuss physician's prescription with customers nor disclose to them the composition of the prescriptions.</p>	
3	e)	<p>Why DEC was formed? Give recommendations of DEC.</p> <p>Why DEC was formed (1M)</p> <p>In the dealing of drugs and medicines, profit rather than service became the main motive. Spurious, substandard and adulterated drugs become more common than standard and the genuine ones. Outside India, drugs were manufactured specifically for India which were of inferior quality. India become platform for quack medicines and adulterated drugs manufactured in all parts of the world. There were very occurrences of offences related to drugs. There was no authority to control such activities.</p> <p>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 was formed to study problems related to drugs in India.</p> <p>Recommendations of DEC (2M)</p> <p>1) Formation of Central Pharmacy Council and the Provincial (State) Pharmacy Council which would look after the education and training of professionals. These councils would maintain the register containing the names and addresses of registered pharmacist.</p> <p>2) It suggested the creation of drug control machinery (departments) at the centre with the branches in all the states.</p> <p>3) Recommended the establishment of a well-equipped CDL with competent staff and experts for an efficient and speedy working of Drug Ctrl Department. It also suggested small laboratories which would work under the guidance of CDL.</p>	<p>1M</p> <p>DEC</p> <p>2M ,</p> <p>Any4</p>



		<p>4)Setting of test laboratories in all states to control the quality of production of drugs and pharmaceuticals.</p> <p>5)Appointment of Advisory board to advise Government in making rules.</p> <p>6)The drugs industry in India should be developed.</p> <p>7)Setting of courses for training in pharmacy.</p> <p>8)Prescribing minimum qualification for registration of pharmacist.</p>																						
3	f)	<p>Write the difference between Law and Ethics.</p> <table><tr><th>Sr. No</th><th>Law</th><th>Ethics</th></tr><tr><td>1</td><td>Definition- Rules of human conduct binding on all persons in a state.</td><td>Definition- Rules by which a profession regulates action & sets standards for all its members.</td></tr><tr><td>2</td><td>Law may prevent one from causing injury to another but it cannot force him to help his neighbour in hours of need.</td><td>Helping the neighbour is the function of ethics.</td></tr><tr><td>3</td><td>A law is something you must obey</td><td>Ethics is how society expects you to behave.</td></tr><tr><td>4</td><td>Law deals with actions that are punishable.</td><td>Ethics deals with right & wrong.</td></tr><tr><td>5</td><td>Laws are written & approved documents.</td><td>Ethics are also written words but they are not carrying legal status</td></tr><tr><td>6</td><td>If law is broken, a violator may be subjected to punishment, a fine or imprisonment.</td><td>If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges</td></tr></table>	Sr. No	Law	Ethics	1	Definition- Rules of human conduct binding on all persons in a state.	Definition- 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 neighbour 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	<p>3M,</p> <p>Any 3</p>
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4		Attempt any FOUR of the followings	12M																					
4	a)	<table><tr><th colspan="3">Differentiate between bonded and non-bonded manufactory or laboratory</th></tr><tr><th>Sr. No</th><th>Bonded Laboratory</th><th>Non-bonded Laboratory</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>Excise duty payable on removal of goods from bonded laboratory.</td><td>Excise duty payable at the time of spirit purchase.</td></tr><tr><td>3.</td><td>Bonded laboratory to function under Excise staff.</td><td>No excise staff is required.</td></tr><tr><td>4.</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>5.</td><td>Suitable for large scale manufacture</td><td>Suitable for small scale manufacture</td></tr></table>	Differentiate between bonded and non-bonded manufactory or laboratory			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.	Suitable for large scale manufacture	Suitable for small scale manufacture	3M , Any 3
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4	b)	<p>What procedure should be followed by drug Inspectors while sending the samples for test or analysis?</p> <p>Following is the procedure to be followed by the drug Inspector while sending the samples for test or analysis-</p> <p>An Inspector taking any samples should pay its fair price and may require a written acknowledgement for the same. If the price tendered is refused or where the Inspector seizes the stock of any drug or cosmetic, he should issue a receipt for the same in the</p>	3M																					

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		prescribed form. He should also inform the purpose of taking the samples unless he will fully absents himself and divide the samples into four parts in his presence. Each portion is then sealed effectively and suitably marked. The person from whom the sample is taken should be permitted to add his own seal and mark to all or any of the portions sealed or marked. If the sample is taken from manufacturing premises, it should be divided into three portions only. Where the sample is made up in containers in small volume or is likely to deteriorate or be damaged by exposure, the Inspector should take three or four such containers after suitably marking them and when necessary, sealing them. One portion of the sample should be restored to the person from whom it was taken, the second portion is sent to the Government Analyst for test or analysis, the third one is preserved for production before the court if required, and the fourth portion is sent to the warrantor, if any.	
4	c)	Mention the duties of government analyst. 1) To analyze or test the samples of drugs & cosmetics sent to him by Drug Inspectors or other persons or 2) To furnish reports of results of such analysis & test. 3) <u>Research work</u> - To forward to the Govt., the report of Analytical & Research work with view to their publication	3M
4	d)	Define the following as per DPCO, 1995. (i) Bulk drug - means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopoeial or other standards specified in the second schedule to the Drugs and Cosmetics Act and which is used as such or as an ingredient in any formulation. (ii) 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.	1 ½ M Each

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		(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.	
4	e)	<p>Give the offences and penalties under DPCO, 1995</p> <p>Penalties.—Any contravention of any of the provisions of this order shall be punishable in accordance with the provisions of the essential commodities act.</p> <p>(1) If any person contravenes any order made under Section 3,</p> <p>(a) he shall be punishable,—</p> <p>(i) in the case of an order made with reference to clause (h) or clause (i) of sub-section (2) of that section, with imprisonment for a term which may extend to one year and shall also be liable to fine, and</p> <p>(ii) in the case of any other order, with imprisonment for a term which shall not be less than three months but which may extend to seven years and shall also be liable to fine:</p> <p>Provided that the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than three months;</p> <p>(b) any property in respect of which the order has been contravened shall be forfeited to the Government;</p> <p>(2) If any person to whom a direction is given under clause (b) of sub-section(4) of section 3 fails to comply with the direction, he shall be punishable with imprisonment for a term which shall not be less than three months but which may extend to seven years and shall also be liable to fine:</p> <p>Provided that the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than three months. or six months, as the case may be.</p> <p>(3) Where a person having been convicted of an offence under sub-section (1) is again convicted of an offence under that sub-section for contravention of an order in respect of an essential commodity, the court by which such person is convicted shall, in addition to any penalty which may be imposed on him under that sub-section, by order, direct that that person shall not carry on any business in that essential commodity for such period, not being less than six months, as may be specified by the Court in the Order.</p>	3M

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4	f)	<p>What qualifications are required for a person to be appointed as “Government Analyst”?</p> <p>For the appointment as a Government Analyst, a person should be:-</p> <p>1. A graduate in medicine/science/ pharmacy/pharmaceutical chemistry of a recognized University, and has had not less than five years post graduate experience in the testing of drugs in a laboratory under the control of</p> <p>i) a Government Analyst or</p> <p>ii) head of an approved institution or testing laboratory or has completed two years training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory, or</p> <p>2. A post graduate in medicine/science/ pharmacy/pharmaceutical chemistry of a recognized University or Associateship Diploma of the Institution of Chemists (India) obtained by passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years of experience in the testing of drugs in the laboratory under the control of</p> <p>i) a Government Analyst or</p> <p>ii) head of an approved institution or testing laboratory or has completed two years training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory.</p>	3M
5		Attempt any FOUR of the followings	12M
5	a)	<p>What do schedule R, schedule J and schedule X to D and C Act,1940 prescribe?</p> <p>Schedule R- Standards for condoms made up of rubber latex intended for single use and other mechanical contraceptives.</p> <p>Schedule J- List of diseases and ailments which a drug may not claim to prevent or cure .</p> <p>Schedule X- List of habit forming, psychotropic and other such drugs.</p>	1M Each
5	b)	<p>Give the schedules for following drugs:</p> <p>(i)Vasopressin</p>	



		<p>(ii) Tolbutamide</p> <p>(iii) Insulin</p> <p>(iv) Ibuprofen</p> <p>(v) Barbituric acid</p> <p>(vi) Betamethasone</p> <p>(i) Vasopressin - Schedule H</p> <p>(ii) Tolbutamide – Schedule G</p> <p>(iii) Insulin - Schedule C , Schedule G</p> <p>(iv) Ibuprofen – Schedule H</p> <p>(v) Barbituric acid – Schedule H</p> <p>(vi) Betamethasone – Schedule H</p>	½ Mark each
5	c)	<p>Define the following terms as per MTP Act, 1971</p> <p>(i) Guardian-</p> <p>(ii) Minor</p> <p>(i) Guardian Definition of "Guardian"</p> <p>means a person having the care of a minor or a lunatic.</p> <p style="text-align: center;">OR</p> <p>Person having the care of the 'person of minor' or a 'mentally ill person' {Sec. 2(a)}</p> <p>(ii) Minor Means a person who, under the provisions of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.</p>	1 ½ Mark Each
5	d)	<p>How retail price of drug is to be calculated under DPCO 1995?</p> <p>By applying the following formula, the retail price of the formulation is calculated by the Government.</p> $R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + ED$ <p>Where, R.P.:- Means retail price.</p> <p>M.C.:- means material cost which includes the cost of drugs and other pharmaceutical</p>	1M

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		<p>aids with overages, if any, plus process loss thereon in accordance with the norms specified from time to time by notification in the official Gazette.</p> <p>C.C.:- means conversion cost worked out in accordance with such norms as may be specified by the Government from time to time by notification in the official Gazette.</p> <p>P.M.:- means the cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the Government from time to time.</p> <p>P.C.:- means packing charges worked out in accordance with such norms as may be specified by Government every year by notification in the Official Gazette.</p> <p>MAPE :- Maximum allowable post manufacturing expenses.</p> <p>In means all the cost incurred by the manufacturer from the stage of ex-factory cost of retailing. It also includes trade margin and margin of manufacturer. MAPE shall not exceed 100% for indigenously scheduled formulations.</p> <p>E.D.:- means excise duty.</p>	<p>Formula</p> <p>2M</p> <p>Explanat</p> <p>ion</p>
5	e)	<p>Give constitution of state pharmacy council.</p> <p>1)Elected members:</p> <p>a) Six members, elected amongst themselves by Registered pharmacists of state.</p> <p>b) One member elected by the members of Medical Council of the State amongst themselves.</p> <p>2)Nominated members:</p> <p>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.</p> <p>3)Ex-officio members:</p> <p>a) Chief administrative medical officer of the State.</p> <p>b) The officer in charge of the drug control organization of the state; appointed under D. & C. Act, 1940.</p> <p>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</p>	3M
5	f)	Mention the conditions under which name of the pharmacist can be removed from	

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		<p>register of pharmacist.</p> <p>The executive committee after giving opportunity to a person to explain his conduct and on sufficient inquiry if satisfied, orders to remove the name of registered pharmacist on following conditions :-</p> <p>(1) If his name has been entered in the register due to error, misrepresentation or suppression of material fact. or</p> <p>(2) If he is convicted of an offence in any professional respect, which in the opinion of Executive Committee considered him unfit as a Registered Pharmacist. or</p> <p>(3) If person employed to work under him in connection with any business of pharmacy has been convicted of an offence or held guilty of an infamous conduct, if such person is registered pharmacist, he is liable to remove his name from register.</p> <p>The removal of names from the register may either be permanent or only for a specified period of time. A person, whose name has been removed from the register is required to surrender his certificate of registration to registrar of the State Pharmacy Council and shall be published in official gazette.</p>	3M
6		Attempt any FOUR of the followings	16M
6	a)	<p>Explain Drug price equalisation account(DPEA) as per DPCO Act,1995</p> <p>Drugs price Equalisation Account (DPEA) –</p> <p>The Government may recover the dues accrued under the provisions of the Drugs (Prices Control) Order, 1979 from the manufacturer, importer or distributor as the case maybe & deposit the same into an account known as Drugs Prices Equalization Account. The amount, from Drugs Prices Equalisation Account shall be utilized for :</p> <p>(i) Paying the shortfall between the retention price and the common selling price or the pooled price as the case may be to the manufacturer or importer or distributor, to increases the production, or to securing the equitable distribution and availability at fair prices, of drugs.</p> <p>(ii) Meeting the expenses incurred by the Government in discharging the functions under</p>	4M

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		this provision & (iii) Promoting higher education and research in Pharmaceutical Sciences and Technology.	
6	b)	<p>Explain what do schedule N to D and C Act,1940 prescribes?</p> <p>Schedule N- List of Minimum equipment's for efficient running of pharmacy:</p> <p>1) Entrance: The front of Pharmacy shall bear an inscription, "Pharmacy".</p> <p>2) Premises: The premises of Pharmacy shall be separate 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 clearly visible and appropriate manner. The area of the section to be used as dispensing department shall not be less than 6 sq. meters for one pharmacist working there in with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5meters.</p> <p>The floor of pharmacy shall be smooth & washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable & washable surface devoid of holes, cracks, crevices.</p> <p>A pharmacy shall be provided with supply of good quality water. There shall be separate dispensing department to prevent the admission of the public.</p> <p>3) Furniture: A pharmacy shall contain furniture of required size & suitable apparatus. Drugs, chemicals & medicaments shall be kept in a suitable room and suitable containers so as to prevent any deterioration of the contents or of contents of container 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.</p> <p>Every container shall bear a label of appropriate size easily readable with names of medicaments as given in Pharmacopoeias.</p> <p>A pharmacy shall be provided with dispensing bench having impervious and washable top.</p> <p>A pharmacy shall be provided with a cupboard with lock and key for storage of poison &</p>	4M



shall be clearly marked with “POISON” in red letters on a white background.

Containers of all the concentrated solution shall bear the special labels or marking with the words ”To be diluted”.

4) Apparatus and Equipment:

A pharmacy shall be provided with following minimum apparatus:

Balance-dispensing, sensitivity 30 mg

Balance-counter, capacity 3 kg, sensitivity 1 kg

Beakers, lipped assorted sizes

Corks assorted sizes and toppers

Cork extractor

Evaporating dishes

Funnel –glass

Litmus paper-blue and red

Measuring glass cylinder 10, 25, 50, 100 & 500 ml

Mortar & pestle

Ointment slab, porcelain

Pipettes, graduated, 2ml, 5ml, & 10 ml

Scissors

Spatula, glass rods, thermometer, tripod stand, watch glasses, water distillation still, water bath, weights, wire gauze, pill machine, pill boxes, suppository mould.

5) Books:

The pharmacopoeia (current edition)

National formulary of India (current edition)

The Drugs and Cosmetics Act, 1940 and Rules, 1945

The Pharmacy Act, 1948

Narcotic Drugs & Psychotropic Substances Act, 1985.

6) 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 pharmacy shall be properly kept and everything must be in good order & clean.



		<p>All records and registers shall be maintained in accordance with the laws in force. Any container taken from the poison should be replaced therein immediately after use & cupboard is to be locked. The keys of cupboard shall be kept in personal custody of a responsible person.</p> <p>Medicament when supplied shall have labels conforming to the provisions of the laws in force.</p>	
6	c)	<p>Write the functions of pharmacy council of India.</p> <p>Functions of PCI:-</p> <p>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)</p> <p>2) To regulate minimum educational standard. (for this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy & report on the facilities available & decides whether the institution should be recognized or not)</p> <p>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</p> <p>4) To compile & maintain a Central Register for Pharmacist containing names of all persons for the time being entered in the state register.</p> <p>5) Any other functions that may be assigned to the Central Council in the furtherance of the objective of the Pharmacy Act, 1948.</p>	4M (Any 4)
6	d)	<p>Give the conditions for approval of places for termination of pregnancies. State offences and penalties under MTP Act, 1971.</p> <p>Conditions for approval of places for termination of pregnancies – (2 marks)</p> <p><u>Places where pregnancy may be terminated-</u></p> <p>i) A Govt. Hospital or</p>	2M Condition

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		<p>ii) A place approved for the purpose of this Act of Govt.</p> <p><u>Place for the termination of pregnancies shall be approved only if – Conditions :</u></p> <p>1) The Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions and</p> <p>2) The following facilities are provided -</p> <p>a) An operation table and instruments for performing abdominal or gynaecological surgery.</p> <p>b) Anaesthetic equipment, resuscitation equipment and sterilization equipment.</p> <p>c) Drugs and parenteral fluids for emergency use.</p> <p>Offences and penalties- (2 Marks)</p> <p>As per the latest amendments in M.T.P. Act,1971</p> <p>i) The termination of a pregnancy by a person who is not a registered medical practitioner shall be an offence punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.</p> <p>ii) Whoever terminates any pregnancy in a place other than that mentioned in sec.4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.</p> <p>iii) Any person being owner of a place which is not approved under clause (b) of sec.4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.</p>	2M Offences & Penalty (any 2)
6	e)	<p>Describe duties of drug inspector in relation to manufacture of drugs and cosmetics.</p> <p>Duties of Drug Inspector in relation to manufacture of D&C Act,1940</p> <p>1)To inspect atleast twice a year, all premises licenced for manufacturing of drugs within the area allotted to him & to satisfy whether the conditions of licence & provisions of the act and rules thereunder are being observed or not.</p> <p>2) To inspect premises licenced for manufacturing of drugs, specified in Schedule-C & C(1) & to observe process of manufacturing, means employed for standardization & testing of drug & storage conditions & qualification of technical staff and employee & all other details of location, construction, administration of establishment, other things which</p>	4M

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		<p>may likely to affect potency & purity of the product.</p> <p>3) To sent after each inspection a detailed report of inspection to the controlling authority with which conditions of licence and provisions of the act & the rules thereunder being observed and which being not observed.</p> <p>4) To take sample of drugs manufactured in the premises and sent them for test or analysis.</p> <p>5) To check all the records & registers required to be maintained under the rules.</p> <p>6) To institute prosecutions, in respect of breach of the act and rules.</p>	
6	f)	<p>Write the procedure for approval of institution running diploma / degree course in pharmacy</p> <p>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.</p> <p>Inspection:</p> <p>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.</p> <p>ii) Inspectors may also attend any examination, to judge its standards without interfering with its conduct.</p> <p>iii) The inspector then report to the PCI on the facilities available in the institution & on the conduct & standard of the examinations held.</p> <p>Approval:</p> <p>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 &</p> <p>ii) The said course of examination shall be considered as approved for qualifying for registration as pharmacist under the act.</p> <p>Declaration:</p> <p>Declaration of approval made by resolution is passed at a meeting of the PCI & published in the Official Gazette.</p>	4M