



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.

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Q. No	Sub Q. N.	Answer	Marking Scheme
1		Answer any Eight of the followings:	16M
1	a)	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
1	b)	Define Poison. Give the objectives 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. Objectives:- 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 1M
1	c)	Give any two recommendations of DEC Following are some important recommendations of DEC- i) Formation of Central Pharmacy Council & State Pharmacy Council which would look after the education & training of professionals. These councils would maintain the register containing the names & addresses of the registered pharmacists. ii) Creation of Drug Control Departments at the Centre with the branches in all the states. iii) Establishment of well-equipped Central Drug Laboratory (CDL) with expert staff. iv) Appointment of an advisory board to advise the Govt. in making rules. v) The drugs industry in India should be developed. vi) Setting of the test laboratories in all states to control the quality of the production of drugs & pharmaceuticals. vii) Setting of courses for training in pharmacy. viii) Prescribing minimum qualification for registration as pharmacist.	1M each, any2



1	d)	<p>Define Law & Ethics as per the code of ethics</p> <p>Law- i)Rules of human conduct binding on all persons in a state or nation. OR ii)Law is a philosophically discovered set of principles which expresses true nature of things and to which man must conform his conduct. OR iii) Law is a body of agreements of men organized politically into society. OR v) Law is a body of commands of sovereign authority in a politically organized society. OR v) Law is a system of percepts whereby an individual may realize the most complete freedom consistent with like freedom of others.</p> <p>Ethics –i)Rules by which a profession regulates actions & sets standards for all its members. OR ii) Ethics is the science of moral principles and represents a slightly different kind of effort to control human conduct. OR iii) Ethics is an appeal to the conscience and more often than not, it helps the people in trading right paths in all walks of life.</p>	<p>1M (any 1)</p> <p>1M (any 1)</p>
1	e)	<p>What does the Schdule J & Schedule P prescribes as per the D& C Act,1940</p> <p>Schedule J:- List of diseases and aliments which a drug may not claim to prevent or cure. Schedule P:- Life period of drugs.</p>	<p>1M 1M</p>
1	f)	<p>What is the purpose of DPCO</p> <p>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.</p>	<p>2M</p>
1	g)	<p>Define minor and guardian as per Medical Termination of Pregnancy Act,1971</p> <p>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>	<p>1M</p>

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		Guardian :- A person having the care of a minor or a lunatic. OR Person having the care of the 'person of minor' or a 'mentally ill person'	1M (any1)
1	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
1	i)	What are the objectives of Drugs & Magic Remedies 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
1	j)	Give any four examples of Schedule X drugs i)Amobarbital, ix)Ethchlorvynol ii)Amphetamine, x) Phenometrazine iii)Barbital, xi) Glutethimide iv)Cyclobarbital, xii)Secobarbital v)Meprobamate, xiii)Methamphetamine vi)Penobarbital, xiv)Dexamphetamine vii)Methyphenobarbital xv)Phencyclidine viii)Methylphenidate Note: i) Any stereoisometric form of the substance specified in this Schedule, any salt of substance and preparation containing such substances are also covered by this Schedule. ii) Preparations containing the above substances are also covered by this schedule.	½ M each, any4

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1	k)	Define registered pharmacist as per Pharmacy Act,1948 Registered Pharmacist: means a person whose name for the time being is entered in the register of the pharmacists of the state in which he is for the time being residing or carrying on his profession or business of pharmacy.	2M
1	l)	Which additional particulars should appear on the label Schedule X drugs as per D & C Act,1940 Additional particulars should appear on label of Schedule X: i)The symbol XR_x in red conspicuously displayed on the left top corner of the label. ii)The word ' warning '- To be sold by retail on the prescription of a Register Medical Practitioner only.	2M
2		Attempt any FOUR of the followings	12M
2	a)	Define education regulations. What it prescribes? 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 <u>Education Regulations</u> <u>Education Regulations may prescribe –</u> i) Minimum qualification for admission to the course. ii) Nature & period of course of study. iii) Nature and period of practical training to be undertaken after the completion of regular course. (Not less than 500 hrs. covered in a minimum of 3 months in an Institution, Hospital, Pharmacy or Dispensary recognized by Central Govt.) iv) The subjects of examination and the standards to be attained therein. v) The equipment and facilities to be provided by the institutions for the students undergoing approved course of study. vi) Conditions to be fulfilled by institutions giving practical training. vii) Conditions to be fulfilled by authorities holding approved examinations. Central Council before submitting the ER or any amendment thereof, as the case may be to the Central Government for approval, sends copies of draft of ER to all State Governments. Then ER is published in official Gazette by Central Government.	Def. 1M 2M



2	b)	<p>What are the functions of PCI as per the Pharmacy Act,1948 (any 3)</p> <p>1) To prescribe the minimum standards of education required for qualification as a pharmacist (This can be provided by making the rules as education regulations, which prescribes minimum qualification for admission, duration of the course, details of the syllabus, practical training and examination, minimum facilities required for conduct of course, examination & practical training).</p> <p>2) To regulate the minimum educational standard. (For this purpose, Council appoints Inspectors to inspect institutions, providing the minimum standards in education in pharmacy and report on the facilities available and decides whether the institute should be recognised or not.</p> <p>3) To recognise qualifications granted outside territories to which Pharmacy Act 1948 extends for the purpose of qualifying for registration under the said Act.</p> <p>4) To compile and maintain a central register for pharmacist containing names of all persons for the time being entered in the state register.</p> <p>5) The Council has to furnish copies of its minutes and those of executive committee, together with the summary of annual activities and accounts to the central Government.</p> <p>6) Any other function that may be assigned to the Central Council in the furtherance of the objectives of the Pharmacy Act, 1948.</p>	1M each, any 3
2	c)	<p>Define i) Magic Remedies ii) Advertisement as per Drugs & Magic Remedies Act,1954</p> <p>Magic Remedies: It includes a Talisman, Mantra, Kavacha, and any other charm claiming to possess miraculous powers.</p> <p>i) for diagnosis, treatment and prevention of any disease in human beings or animals, or</p> <p>ii) for affecting or altering the structure or organic function of the body of human being or animal.</p> <p>Advertisement: It includes</p> <p>i) Any notice, circular, label, wrapper or otherwise such document, and</p> <p>ii) Any announcement made orally or by means of producing or transmitting light, sound or smoke.</p>	1½ M 1½ M

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2	d)	<p>How retail price of formulations is calculated as per DPCO</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,</p> <p>R.P.:- Means retail price.</p> <p>M.C.:- means material cost which includes the cost of drugs and other pharmaceutical aids with overages, if any, plus process loss thereon in accordance with the norms specified from time to time by notification in the official Gazette.</p> <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>	1M Formula 2M
2	e)	<p>What is the role pharmacist in relation to his profession as per code of ethics</p> <p>Role of pharmacist in relation to his profession</p> <ol style="list-style-type: none">1) A pharmacist should observe the law and ethical principles to maintain the standard of the profession.2) A pharmacist should extend the help and co-operation to his fellow pharmacist in an emergency and legitimate needs.3) A pharmacist should try to weed out the undesirable corrupt or dishonest conduct of the member of his profession maintaining its status in society.4) A pharmacist should have a fair knowledge of laws of the state and nation pertaining to	3M

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		<p>food, drug, pharmacy education, health etc.</p> <p>5) A pharmacist should have an up to date knowledge of professional matters. It should associate himself with various pharmaceutical organizations, the aims and objects of which are compatible with this code of ethics.</p> <p>6) A pharmacist should not perform such acts which will bring discredit to his profession or to himself.</p>	
2	f)	<p>Enlist the operations controlled by Central Government as per NDPS Act,1985 (any six)</p> <p>The operations controlled by Central Government under N.D.P.S. Act, 1985.</p> <p>1) Government shall fix time to time the limits within which licenses may be given for cultivation of opium poppy.</p> <p>2) All opium, the product of land cultivated with opium poppy shall be delivered by cultivators to Officers authorized on behalf of Central Government.</p> <p>3) Central Government may from time to time fix the price to be paid to the cultivators for the opium delivered.</p> <p>4) The rules may prescribe the forms & conditions of licenses for the manufacture, possession, production, purchase, sale, transport, import, export, consumption or use of Psychotropic substances. Fix fees may be charged for such licenses.</p> <p>5) The rules may prescribe the forms & conditions of licenses for cultivation of the opium poppy and production & manufacture of opium. The rule also prescribes the fees that may be charged therefore.</p> <p>6) The rules may prescribe forms & conditions of licenses for manufacture of manufactured drugs & fees that may be charged therefore.</p> <p>7) The rules may provide for the weightment, examination and classification, according to the quality and consistence of the opium received at the factory and the deductions from or additions to the standard price to be made in accordance with the result of examinations.</p> <p>8) The rules may prescribe that opium shall be weighed, examined & classify according to its quality & consistency by the officers authorized in this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator.</p> <p>9) Rules may require that delivered opium by cultivator, if found as a result of examination in the Central Government factory to be adulterated, may be confiscated by the officers authorized in this behalf.</p> <p>10) The rules may prescribe the ports & other places at which any kind of narcotic drugs or psychotropic substances may be imported into India or exported from India or transhipped.</p>	<p>½ M each, any 6</p>

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3		Attempt any FOUR of the followings	12M
3	a)	<p>Give any six classes of cosmetics which are prohibited to be imported as per D and C Act,1940</p> <p>The import of following classes of cosmetics is prohibited.</p> <ol style="list-style-type: none">1) Cosmetics which are not of standard quality or misbranded cosmetics.2) Cosmetics containing Hexachlorophene.3) Cosmetics containing coal tar colour other than one prescribed.4) Cosmetics containing prescribed colours which contain more than 2p.p.m. of arsenic or 20 p.p.m. of lead or 100p.p.m. of heavy metal other than lead.5) Cosmetic intended for use on the eye-brow or eyelash or around the eye containing any Coal Tar Dye colour, Coal tar base or Coal tar dye intermediate.6) Cosmetics containing mercury compounds.7) Cosmetics containing any ingredients which may render them unsafe or harmful for use.8) Cosmetics coloured with arsenic or lead compounds. <p>However, small quantities of cosmetics, the import of which is otherwise prohibited , may be imported for personal use if,</p> <ol style="list-style-type: none">i) They form part of passengers baggage and for the bonafide use of the passenger.ii) They are declared to the customs authority	½ M each, any6
3	b)	<p>What are the bonafide reasons for termination of pregnancies by RMP as per Medical Termination of Pregnancy Act,1971?</p> <p>1) Consent:-</p> <p>No pregnancy shall be terminated by a RMP without the consent of the pregnant women except:</p> <ol style="list-style-type: none">i) When the pregnant woman is less than 18 yrs. of age orii) The pregnant woman is lunatic. <p>In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian.</p>	3M



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.

3

c)

Differentiate between bonded and non-bonded laboratory as per Medicinal and Toilet Preparation(E.D.) Act, 1955.(any three points)

1M each, any3

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.

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		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	
3	d)	Write the qualifications of Drug Inspector as per D & C Act, 1940. A person who is appointed an Inspector should possess the following qualifications Graduate in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized University. Provided that for the purpose of inspection of manufacture of substances specified in Schedule C, a person appointed as a Drug Inspector should have – i) Not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C, or ii) Not less than 18 months experience in testing of at least one of the substances in Schedule C in a approved Laboratory, or iii) Not less than three year's experience in the inspection of firms manufacturing any of the substances specified in Schedule C during the course of their services as Drugs Inspector. Provided further that the first 4 years from the date on which Chapter IV of the Act takes effect in the States, person whose qualification, training & experience are considered adequate may be appointed as Inspector & their appointments continued even after 4 years, if the State Govt. is satisfied.			3M
3	e)	Under what conditions the name of pharmacist is removed from the register as per Pharmacy Act, 1948? 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			3M

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		<p>following <u>conditions</u> :-</p> <p>(i) If his name has been entered in the register due to error, misrepresentation or suppression of material fact. or</p> <p>(ii) 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>(iii) 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><u>Provided that no such order shall be made under clause (iii) unless the Executive Committee is satisfied-</u></p> <p>(a) that the offence or infamous conduct was instigated or connived at by the registered pharmacist, or</p> <p>(b) that the registered pharmacist has at any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place committed a similar offence or been guilty of similar infamous conduct,</p> <p>(c) that where the offence or infamous conduct continued over a period , the registered pharmacist had, or reasonably ought to have had, knowledge of the continuing offence or infamous conduct</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>	
3	f)	<p>Give any three offences and respective penalties in relation to Medical Termination of Pregnancy Act, 1971.</p> <p><u>As per the latest amendments in M.T.P. Act,1971</u></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>	1M for each, any 3

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		<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>	
4		Attempt any FOUR of the followings	12M
4	a)	<p>What are various offences and penalties under Pharmacy Act, 1948?(any three)</p> <p>1) Falsely claiming to be Registered Pharmacist: Any person whose name is not entered in the register falsely claims to be a registered pharmacist or uses in connection with his name any words or letters to suggest that his name is so entered in the register is punishable with fine up to five hundred rupees on first conviction, and with imprisonment upto six months or with fine up to thousand rupees or both on any subsequent conviction. The use of description such as ‘Pharmacist’, ‘Chemist’, ‘Druggist’, ‘Pharmaceutist’, ‘Dispenser, ‘Dispensing Chemist’ or any combination of such words by a person indicates that his name is entered in the register of a state.</p> <p>2) Dispensing by unregistered persons: The persons other than registered pharmacist dispensing any medicine for patients is liable for punishment with imprisonment upto six months or with fine upto one thousand rupees or with both.</p> <p>3) Failure to surrender certificate of registration: Is also punishable with fine upto fifty rupees.</p> <p>4) Obstructing State Pharmacy Council Inspectors :- Penalties :- Shall be deemed guilty of an offence & may be punished with imprisonment upto six month or fine upto 1000 Rs or both</p>	1M for each, any 3
4	b)	<p>Mention the classes of advertisements which are exempted under DMR Act, 1954.(any six)</p> <p>Classes of exempted advertisements:</p>	

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		<p>1. Any advertisements relating to the drugs printed or published by the Government or any other person with prior permission of the Government.</p> <p>2. Any advertisement relating to a drug which is sent confidentially in the prescribed manner to registered medical practitioner.</p> <p>3. Advertisements including any book or treatise dealing with any matter relating to the diseases, disorders or conditions which are otherwise prohibited provided published from bonafide scientific or social point of view.</p> <p>4. Displayed signboards or notices by registered medical practitioners on his premises indicating that the treatment is undertaken for any disease, disorders or conditions specified in the schedule to this Act or in the rules made under this Act.</p> <p>5. Advertisements relating to the drugs which comply with the required conditions as follows:</p> <p>(a) Leaflets or literature along with packing of drugs; or advertisements of drugs in medicinal, pharmaceutical, scientific and technical journals</p> <p>(b) Therapeutic index or price list published by licensed manufacturer, importer or distributor of drugs or medical literature distributed by medical representatives.</p> <p>With conditions that:</p> <p>6. The advertisement should contain only the information required for the guidance of registered medical practitioner regarding:</p> <p>(a) therapeutic indications;</p> <p>(b) route of administration;</p> <p>(c) dosage and side effects of such drug or drugs; and</p> <p>(d) the precautions to be taken in treatment with the drug</p> <p>7. The distribution of such literature should be given to registered medical practitioner, dispensaries, hospitals, medical and research institutions, chemists and druggists or pharmacies</p>	½ M for each, Any6
4	c)	<p>Explain the role of pharmacist in health care system.</p> <p>i) All the pharmacists working in different fields of profession are directly or indirectly related to nation's health.</p> <p>ii) Community pharmacist and hospital pharmacists are health professionals for the safe</p>	3M

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		<p>and effective use of drugs.</p> <p>iii) Pharmacy occupies an important position in the health care system. So the pharmacist should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product.</p> <p>iv) Pharmacist is legally held responsible for the quality of product which is manufactured and distributed.</p> <p>v) They supply medicines against prescriptions. They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes.</p> <p>vi) They provide link between Physician & Patient</p> <p>vii) They are able to advice patients with minor illness viii) The profession of Pharmacy presently consist of</p> <ul style="list-style-type: none">• Industrial pharmacist• Hospital pharmacist• Academic pharmacist• Community pharmacist <p>ix) Pharmacist has to play an important role in areas such as:</p> <ol style="list-style-type: none">1. Prescription adherence.2. Storage and distribution of drugs.3. Drug choice.4. Drug monitoring.5. Information and education.6. Clinical pharmacokinetics.7. Research and development and many other health activities	
4	d)	<p>Define pharmacy, chemist and druggist and drug store as per D&C Act, 1940.</p> <p>Pharmacy: Licensed premises for the sale of drugs which require the services of a “Qualified Person” and where the drugs are compounded against the prescriptions.</p> <p>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.</p>	1 mark for each def.

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		Drug Store: Licensed premises for the sale of drugs, which do not require the services of a qualified person.	
4	e)	Give the objective of Medicinal and Toilet Preparation Act, 1955 and define toilet preparation as per Medicinal & Toilet Preparation Act, 1955. Objectives The act provides for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drugs and narcotics. Toilet Preparations: 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.	1½ M 1½ M
4	f)	How pharmacist should handle the prescription as per the code of pharmaceutical ethics? Prescription- i) Prescriptions should not be discussed with patients or others regarding the merits and demerits of their therapeutic efficiency. ii) After receiving the prescriptions, a pharmacist should not even show any expression on his face so that the patients will lose their faith in the physicians or prescribers. iii) No addition, omission or substitution of ingredients in a prescription should be made without the consent of prescriber or physician whenever possible except in an emergency. iv) In case of any error in the prescription, it should be referred back to the prescriber for necessary correction. v) If at all change in prescription is necessary in the interest of the health of the patient, it should not affect the reputation of the physician. vi) A pharmacist should not recommend any particular prescriber unless he is specially asked to do so.	3M

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5		Attempt any FOUR of the followings	12M
5	a)	<p>Give the functions of CDL as per D & C Act, 1940 (any six).</p> <p>1)To analyse or test the samples of drugs or cosmetics sent to it by Custom collectors or any other authorized officers or courts</p> <p>2)To carry out such other duties as may be entrusted to it by Central or State Govt. after consultation with the DTAB</p> <p>3) In case of the following drugs or classes of drugs, function of CDL carried out at the Central Research Institute, Kasauli, and such functions are exercised by the Director of the said Institute:-</p> <p>Sera, Solution of serum proteins intended for injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature and sterilized surgical suture & Bacteriophages.</p> <p>4)The functions regarding Oral Polio Vaccine are exercised by the Deputy Director & Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute Kasauli.</p> <p>5)In case of the following drugs or classes of drugs shall be carried out at the Indian Veterinary Research Institute, Izatnagar or Mukteshwar. Such functions are exercised by the Director of either of the said institutes:</p> <p>Anti-sera, Vaccines, (Toxoids, Diagnostic Antigens for veterinary use.</p> <p>6) In case of condoms the functions of CDL are carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad, and such functions are exercised by the Director of the said Laboratory.</p> <p>7)In case of VDRL Antigen (Venereal Disease Ref. Lab.) the functions of CDL are carried out at Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions are excersied by Director of Serologist and Chemical Examiner of the said Laboratory.</p> <p>8)In respect of Intrauterine Devices and Felope Rings, the functions of laboratory shall be carried out at the Central Drug Testing Laboratory, Thane, Maharashtra and such functions shall be exercised by the Director of the said Laboratory.</p> <p>9)In respect of human blood and human blood products including components, to test for</p>	<p>½ M each, any 6</p>

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		<p>freedom of HIV antibodies, shall be carried out by the following Institutes, Hospitals and such functions are exercised by the head of the respective Institutes-</p> <p>a) National Institutes of Communicable Disease, Department of Microbiology, Delhi.</p> <p>b) National Institute of Virology, Pune</p> <p>c) Centre of Advanced Research in Virology, Christian Medical College, Vellore.]</p> <p>10)In respect of Homoeopathic medicines the function of CDL carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said laboratory</p> <p>11)In respect of Blood Grouping reagent and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus the function of CDL carried out at the National Institute of Biologicals, NOIDA and such functions are exercised by the Director of the said laboratory.</p>	
5	b)	<p>Enlist qualifications for entry on the first register under Pharmacy Act, 1948.</p> <p>Qualifications for entry on first register.-</p> <p>Any person who is eighteen years old entitled to have his name in first register on payment of the prescribed fee, if he resides or carries on the business or profession of pharmacy in the state and should have the following <u>qualification</u>:-</p> <p>i)A degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University, or State Government or a prescribed qualification granted by an authority outside India, or</p> <p>ii) A degree other than a degree in pharmacy or pharmaceutical chemistry and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for total period of not less than 3 years or iii)Has passed an examination recognized as adequate by State Government for compounders and dispensers, or</p> <p>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.</p>	3M

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5	c)	<p>List the facilities provide for and ‘Approval of places for termination of pregnancy’ under M. T. P. Act, 1971.</p> <p>Facilities :-</p> <p>Upto <u>12 weeks MTP</u> : Places may be approved with following facilities :{Rule-5(1) (ii)}</p> <ul style="list-style-type: none">• Gynaecology Examination Table/ Labour Table,• Resuscitation and Sterilisation equipment,• Drugs & Parental Fluids,• .Backup facilities for treatment of shock, &• Facilities for Transportation. <p>Upto <u>20 weeks MTP</u> :Places may be approved with following facilities :{Rule-5(1) (ii)a,b,c}</p> <ul style="list-style-type: none">• An operation table and• instruments for performing abdominal or Gynecological surgery.• Anaesthetic Equipments, Resuscitation and Sterilisation equipment.• Drugs and parenteral fluids for emergency use, as notified by Government of India from time to time <p>Approved places for termination of pregnancy:</p> <p>The pregnancy may be terminated by RMP only at</p> <ol style="list-style-type: none">1. A hospital established or maintained by Government2. A place for the time being approved for the purpose of this Act by the Government.3. A place approved by ‘District Level Committee’ (D.L.C.)	<p>2M</p> <p>1M</p>
5	d)	<p>What are the various labeling requirements for ophthalmic preparations as D & 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>2M</p>

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		<p>i) The statement ‘Use the solution within one month after opening the container’.</p> <p>ii) Name and concentration of the preservative used.</p> <p>iii) The words ‘NOT FOR INJECTION’.</p> <p>iv) Special instructions regarding storage, wherever applicable.</p> <p>v) A cautionary legend reading as:</p> <p>WARNING-</p> <p>i) If irritation persists or increases, discontinue the use & 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
5	e)	<p>Describe Schedule N in brief as per D & C Act, 1940.</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.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.</p>	3M

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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.

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

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

A pharmacy shall be provided with a cupboard with lock and key for storage of poison & 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.

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		<p>5) Books:</p> <p>The pharmacopoeia (current edition)</p> <p>National formulary of India (current edition)</p> <p>The Drugs and Cosmetics Act, 1940 and Rules, 1945</p> <p>The Pharmacy Act, 1948</p> <p>Narcotic Drugs & Psychotropic Substances Act, 1985.</p> <p>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> <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>	
5	f)	<p>Define:</p> <p>(i) Dutiable goods as per M. T. P. (E. D.) Act, 1955.</p> <p>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.</p> <p>(ii) Restricted preparation as per Medicinal and Toilet Preparation Act, 1955.</p> <p>Restricted Preparation: These are medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages.</p>	<p>1½ M</p> <p>1½ M</p>
6		Attempt any FOUR of the followings	16M
6	a)	<p>Give ex-officio members of DTAB.</p> <p>i) The Director General of Health Services, who shall be Chairman of the board.</p> <p>ii) The Drugs Controller of India.</p> <p>iii) The Director of the Central Drugs Laboratory, Calcutta.</p>	4M

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		<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>	
6	b)	<p>Explain essential requirements of bonded Laboratory.</p> <p>Following are the requirements of the bonded laboratory</p> <ol style="list-style-type: none">1) The spirit store (if a distillery or rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory.)2) Room or rooms for manufacture medicinal preparations.3) One or more rooms for storing finished medicinal preparations.4) A separate room or arrangement for manufacture of toilet preparations.5) The storage room for the finished toilet preparations.6) Accommodation near the entrance for the officer in-charge with necessary furniture.7) Every room in the bonded laboratory should bear a board indicating the name of the room & serial number.8) The pipes form sinks or wash basins in the laboratory should be connected with the general drainage of the laboratory.9) The arrangements of gas & electric connections should be such that their supply can be cut off at the end of day's work.10) Every window in the laboratory would specific arrangement of malleable iron rods of prescribed dimensions and the window should be covered on the inside with strong wire netting of mesh not exceeding 25mm.11) There shall only one entrance to the bonded laboratory & one door to each of its compartments. All the doors shall be secured with excise ticket locks in the absence of the officer-in-charge.12) All vessels intended to hold alcohol & other liquid preparations should bear distinctive serial no. with their full capacity marked individually.	4M

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		<p>vi) To make enquiries & inspections regarding the sale of drugs in contravention to the Act.</p> <p>vii) To detain the imported packages, if he suspects to contain drugs, the import of which is prohibited.</p>	
6	e)	<p>Enlist any four offences and penalties for same as per Medicinal and Toilet Preparation Act, 1955.</p> <p><u>Offence-</u></p> <p>1) a) Contravention of any of the provisions relating to the terms & conditions of a license granted under the Act, or</p> <p>b) Failure to pay any duty of excise payable under this Act, or</p> <p>c) Failure to supply required information or supplying false information or</p> <p>d) Attempt to commit or abet any of the above offence</p> <p><u>Penalty-</u> Imprisonment upto 6 month or Fine upto 2000/- or with both</p> <p>2) Connivance by any owner or occupier of land or by any agent of such owner or occupier for any offence against the provision of this Act, or rules there under.</p> <p><u>Penalty-</u> Imprisonment upto 6 months or Fine upto 500/- or both for every offence</p> <p>3) Vexatious search, seizure by any officer exercising powers under this Act or rules there Under. <u>Penalty-</u> Fine upto 2000/-</p> <p>4) Refusal to perform or withdrawal of oneself from duty by the Excise Officer without permission of the superior officer.</p> <p><u>Penalty -</u> Imprisonment upto 3 month or Fine upto three months pay</p> <p>5) Failure to furnish proof of export within the prescribed period to the satisfaction of Excise Commissioner by any persons authorised to export dutiable goods in bond.</p> <p><u>Penalty-</u> Fine upto 2000/- extend to twice the amount of duty.</p> <p>6) Of all the offences committed with respect to warehousing</p> <p><u>Penalty-</u> Fine upto 2000/- & goods related to the offences are liable for confiscation</p> <p>7) Obstruction to the officers while exercising their powers regarding Entry, Search &</p>	1M each, any 4

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		<p>Seizure</p> <p>Penalty- Fine upto 600/-</p> <p>8)Prosecution:- Only the sub-inspector or officer above his rank can institute the prosecution under this act</p> <p>9)Arrests: - Only the sub-inspector or officer above his rank can make arrest under this Act.</p> <p>10)A breach of the rules, where no punishment is provided.</p> <p>Penalty- Fine upto 1000/-and confiscation of the goods</p> <p>11)Keeping of stocks of dutiable goods in disorderly manner (not in accordance with the provision of this Act.)</p> <p>Penalty- Fine upto Rs. 1000/-</p> <p>12)Maintaining false accounts of stock of goods in a manufactory or warehouse or not following the provision of this Act while maintaining such accounts</p> <p>Penalty- Fine upto Rs. 2000/-</p> <p>13)Sale of dutiable good except in prescribed containers bearing a label.</p> <p>Penalty- Fine upto 1000/- & confiscation of the goods related with this offence.</p> <p>14)Disclosure of information by Excise officers learned by him in his official capacity.</p> <p>Penalty- Fine upto 1000/-</p>	
6	f)	<p>Define ‘Bulk drugs’ under DPCO. Explain in brief about Drug Price Equalisation Account.</p> <p>Bulk Drug means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation.</p> <p>Drugs Prices Equalisation Account.</p> <p>The Government may by recover the dues accrued under the provisions of the Drugs (Prices Control) Order, 1979 from the manufacturer, importer or distributor as the case maybe & deposit the same into an account known as Drugs Prices Equalization Account.</p>	<p>2M</p> <p>2M</p>



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The amount, from Drugs Prices Equalisation Account shall be utilised for :

- i) Paying the shortfall between the retention price and the common selling price or the pooled price as the case may be to the manufacturer or importer or distributor, to increase the production, or to securing the equitable distribution and availability at fair prices, of drugs.
- ii) Meeting the expenses incurred by the Government in discharging the functions under this provision &
- iii) Promoting higher education and research in Pharmaceutical Sciences and Technology.