WINTER– 2023 EXAMINATION

Model Answer – Only for the Use of RAC Assessors

Subject Name: **Pharmacy Law & Ethics** **Subject Code:** 20226

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.
8) As per the policy decision of Maharashtra State Government, teaching in English/Marathi and Bilingual (English + Marathi) medium is introduced at first year of AICTE diploma Programme from academic year 2021-2022. Hence if the students write answers in Marathi or bilingual language (English +Marathi), the Examiner shall consider the same and assess the answer based on matching of concepts with model answer.

Q. No.	Sub No.	Answers	Marking Scheme
1		**Answer any SIX of the following:**	**30M**
1	a)	**Discuss the qualification and Duties of Drug Inspector** **Marking Scheme: Qualification -2 M, Duties- in relation to sale -1.5M (Any three) In relation to manufacture- 1.5M marks (Any three)** **Answer: Qualification of Drug Inspector:** A person who is appointed an Inspector should possess the following qualifications 1) 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 years 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	5

Q. No.	Sub No.	Answers	Marking Scheme
		considered adequate may be appointed as Inspector & their appointments continued even after 4 years, if the State Govt. is satisfied. **Duties of Drug Inspectors in relation to sale of drugs and cosmetics-** 1) To inspect at least twice a year all establishments licensed for sale of drugs in the area assigned to him and to check whether the conditions of the licenses are observed or not. 2) If he thinks necessary, to obtain and send the samples of imported drugs and cosmetics for test or analysis, which are being sold or stocked in contravention of the provisions of the Act. 3) To investigate any complaint in writing made to him. 4) To institute prosecutions in case of breach of the Act and Rules. 5) To maintain the records relating to all inspections and actions taken by him and to submit copies of such records to the controlling authority. 6) To make inquiries and inspections regarding the sale of drugs in contravention of the provisions of the Act. 7) To detain the imported packages, if he suspects to contain drugs, the import of which is prohibited. **Duties of Drug Inspector in relation to manufacture of drugs and cosmetics.** Duties of Drug Inspector in relation to manufacture of D&C Act,1940 1)To inspect at least 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. 2) To inspect premises licenced for manufacture of drugs, specified in Schedule-C & C(1) & to observe process of manufacturing, means employed for standardization & testing of drug & storage conditions & qualification of technical staff and employee & all other details of location, construction, administration of establishment, other things which may likely to affect potency & purity of the product. 3) To send 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. 4) To take sample of drugs manufactured in the premises and sent them for test or analysis. 5) To check all the records & registers required to be maintained under the rules. 6) To institute prosecutions, in respect of breach of the act and rules.	

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Q. No.	Sub No.	Answers	Marking Scheme
1	b)	**Discuss the constitution and function of PCI** **Marking Scheme: Constitution- 3 M, Functions- 2 marks (Any 4)** **Answer: Constitution of PCI** **Elected Members** i) 6 members, among whom there shall be at least 1 Teacher of each of subject Pharmaceutical Chemistry, Pharmacy, Pharmacology & Phamacognosy elected by UGC, from among persons on the teaching staff of an Indian University or a college affiliated which grants degree or diploma in pharmacy. ii) 1 member elected from amongst themselves by the members of Medical Council of India iii) 1 member from each state elected by the members of the State Council amongst themselves who shall be a Registered Pharmacist **Nominated Members** i) 6 members nominated by the Central Government of whom at least 4 shall be possess degree or diploma in Pharmacy & practicing Pharmacy or Pharmaceutical Chemistry ii) 1 member from each state, nominated by State Government who shall be Registered Pharmacist **Ex-officio members**: - i) Director General of Health Services, who shall be Chairman ii) Drug Controller of India iii) Director of the Central Drug Laboratory (CDL) **Functions of PCI** **1)**To prescribe the minimum standard of education required for qualification as a Pharmacist (This can be provided by making rules as Education Regulation which prescribes minimum qualification for admission, duration of course, details of syllabus, practical training, examination, minimum facilities required for the conduct of course, examination & practical training) **2)** To regulate minimum educational standards. (For this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy and report on the facilities available & decides whether the institution should be recognized or not) **3)** To recognize qualification granted outside the territories to which Pharmacy Act,1948 extends for the purpose of qualifying for registration under the said Act **4)** To compile & maintain a Central Register for Pharmacist containing names of all persons for the time being entered in the state register. **5)** Any other functions that may be assigned to the Central Council in the furtherance of the objective of the Pharmacy Act,1948.	5

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Q. No.	Sub No.	Answers	Marking Scheme
1	c)	**What is clinical trial and explain various phases of clinical trial.** **Marking Scheme: Clinical trial- 1 M, Phases- 4 M** **Answer: Clinical trial** Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. Clinical trials are scientific investigations that examine and evaluate safety and efficacy of different therapies in human subjects. **Various phase of clinical trial** **Phases of Clinical Trials** **Phase I trial:** This phase is called as **'**Human Pharmacology'. It usually tests new drugs for the first time in a small group of often healthy people (20 to 80) to judge its safety and side effects and to find the correct drug dosage. **Phase II trial**: This phase is called as 'Therapeutic exploratory trial'. It is conducted on comparatively larger and homogeneous populations. It lasts for long period. The number of subjects involved are 100-300. The primary objectives are - i)To evaluate the effectiveness of a drug for particular indications in patients with the condition to be treated, diagnosed or prevented. ii) To determine common short term side effects and risk associated with the drug. iii) To determine dose and dosage regimen for Phase III trials **Phase III trials**: It is called as 'Therapeutic confirmatory trials'. Phase III Trial gathers more information about safety and effectiveness, studying different populations and different dosages, using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. These trials last for several years. It involves expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather additional information to evaluate the benefit-risk relationship of the drug. **Phase IV trials**: Phase IV trials are 'Post Marketing Trials'. It includes post marketing studies to describe additional information including drug's risks, benefits and optimal use. It is conducted in large and diverse populations. It is conducted for long period for determination of drugs safety, efficacy and dose definition.	**5**

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Q. No.	Sub No.	Answers	Marking Scheme
1	d)	**Discuss the various functions of CDL as per Drugs and Cosmetics Act, 1940** **Marking Scheme: Functions-5 M (any 10)** **Answer: Functions of CDL** **1)** To analyze or test the samples of drugs or cosmetics sent to it by Custom collectors or any other authorized officers or courts **2)** To carry out such other duties as may be entrusted to it by Central or State Govt. after consultation with the DTAB **3)** In case of the various drugs or classes of drugs such as Sera, Solution of serum proteins intended for injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature and sterilized surgical suture & Bacteriophages, functions of CDL is carried out at the Central Research Institute, Kasauli, and such functions are exercised by the Director of the said Institute. **4)**The functions regarding Oral Polio Vaccine are exercised by the Deputy Director & Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute Kasauli. **5)**In case of the various drugs or classes of drugs such as Anti-sera, Vaccines, Toxoids, Diagnostic Antigens for veterinary use 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 **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.	5

Q. No.	Sub No.	Answers	Marking Scheme
		7) In case of **VDRL Antigen (Venereal Disease Ref. Lab.)** the functions of CDL are carried out at Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions are exercised by Director of Serologist and Chemical Examiner of the said Laboratory. **8)** In respect of Intrauterine Devices and Felope Rings, the functions of laboratory shall be carried out at the Central Drug Testing Laboratory, Thane, Maharashtra and such functions shall be exercised by the Director of the said Laboratory. **9**)In respect of human blood and human blood products including components, to test for freedom of HIV antibodies, shall be carried out by the following Institutes, Hospitals and such functions are exercised by the head of the respective Institutes- **i)** National Institutes of Communicable Disease, Department of Microbiology, Delhi. **ii**) National Institute of Virology, Pune **iii**) Centre of Advanced Research in Virology, Christian Medical College, Vellore. **10)**In respect of Homoeopathic medicines the function of CDL carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said laboratory **11)**In respect of Blood Grouping reagent and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus the function of CDL carried out at the National Institute of Biologicals, NOIDA and such functions are exercised by the Director of the said laboratory.	

1	e)	**What is the role of a pharmacist in relation to his job as per code of ethics?** **Marking Scheme: 5M (1 M for each point)** **Answer: Role of a pharmacist to his job** **1. Pharmaceutical services:** i) A pharmacist should provide efficient and reasonably comprehensive pharmaceutical services through the medical store or pharmacy. ii) Such services should include supply of commonly required medicines without undue delay and furnishing the emergency supply at all times. **2. Pharmacy/Drug Store:** i) In every pharmacy/ drug store, there should be qualified pharmacist to have personal control the pharmacy. ii) A pharmacy should be planned in such a way that there is no accidental contamination in the preparation, dispensing and supply of medicines. iii) The appearance of the premises should reflect the professional character of pharmacy. **3. Prescriptions:** i) Prescriptions presented for dispensing should not be discussed with patients or others regarding the merits and demerits of their therapeutic efficiency. ii) A pharmacist should not show any expression on his face so that the patients will lose their faith in the physicians or prescribers after receiving the prescriptions. iii) No addition, omission or substitution of ingredients in a Rx should be made without the consent of prescriber 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 or approval of the change suggested. v) If at all change in the prescription is necessary, it should not affect the reputation of physician. vi) A pharmacist should not recommend any particular prescriber unless he is specially asked to do so.	**5**

4. Drugs/Ingredients:

i) While dispensing, the drugs or ingredients should be weighed or measured correctly.

ii) Pharmacist should always use drugs and medicinal preparations of standard quality.

iii) Drugs likely to cause addiction or abuse should not be supplied when there is reason to suppose that it is required for such purpose.

5. Practical Training:

i) While imparting practical training, the in-charge pharmacist should see that the trainees acquire sufficient technique and skill.

ii) No certificate should be granted to the trainee pharmacist before completion of prescribed period of training or without undergoing practical training or unless the trainee acquires sufficient knowledge.

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Q. No.	Sub No.	Answers	Marking Scheme
1	f)	**Give Constitution of DTAB** **Marking Scheme: 5M (2M for Ex-officio members, 1M for nominated members and 2 M for elected members)** **Answer: Constitution of DTAB:** It is constituted by Central Government. It has the following members- **Ex-Officio members of DTAB**: **i**) The Director-General of Health Services, who is the chairman of the Board. ii)The Drug Controller of India iii)The Director of the Central Drug Laboratory, Calcutta iv)The Director of the Central Research Institute, Kasauli v) The Director of the Central Drug Research Institute, Lucknow. vi) The Director of the Indian Veterinary Research Institute, Izatnagar vii)The President, Pharmacy Council of India viii)The President, Medical Council of India **Nominated Members of DTAB** i) Two persons from among persons who are in-charge of the Drugs control in the states are to be nominated by Central Government. ii) One person from the pharmaceutical industry is to be nominated by Central Government. iii) Two Government Analysts are to be nominated by Central Government. **Elected Members of DTAB** i) One teacher in Pharmacy, Pharmaceutical Chemistry or Pharmacognosy on the staff of an university or affiliated colleges is elected by the Executive Committee of Pharmacy Council of India. ii) One teacher in medicine or therapeutics on the staff of an University or affiliated colleges is elected by the Executive Committee of Medical Council of India. iii) One Pharmacologist is elected by the Governing Body of the Indian Council of Medical Research. iv) One person is elected by the Central Council of Indian Medical Association. v) One person is elected by the Council of the Indian Pharmaceutical Association.	5

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Q. No.	Sub No.	Answers	Marking Scheme
1	g)	**Discuss the objectives of DPCO and the Retail Price of Drug is calculated.** **Marking Scheme: Objectives- 2M, Retail price calculation- 3M** **Answer: Objectives of DPCO:** The various objectives of this order are- 1. to make the essential medicines available at reasonable prices. 2. to provide sufficient opportunity for innovation and competition to support the growth of industry. 3. to meet the goals of employment and shared economic growth of all. 4. to achieve adequate production. **Retail Price calculation**: By applying the following formula, the retail price of the formulation is calculated by the Government. R.P.= (M.C.+ C.C.+ P.M. + P.C.) x (1+ MAPE/100) + ED Where, **R.P. :** means retail price. **M.C.:** means material cost 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. **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.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.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. **MAPE: -** Maximum allowable post manufacturing expenses. 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. **E.D.:-** means excise duty.	**5**

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Q. No.	Sub No.	Answers	Marking Scheme
2		**Answer any TEN of the following:**	**30 M**
2	a)	**Define Magic remedies and give exempted advertised under DMR Act,1954. (any four)** **Marking Scheme: Definition- 1M, Classes -2M (Any 4)** **Answer: Magic Remedy:** It includes a Talisman, Mantra, Kavacha, and any other charm alleged to possess miraculous powers. i) for diagnosis, treatment and prevention of any disease in human beings or animals, or ii) for affecting or altering the structure or organic function of the body of human being or animal **Classes of exempted advertisements:(Any 4 classes)** 1. Any advertisements relating to the drugs printed or published by the Government or any other person with prior permission of the Government. 2. Any advertisement relating to a drug which is sent confidentially in the prescribed manner to registered medical practitioner. 3. Advertisements including any book or treatise dealing with any matter relating to the diseases,disorders or conditions which are otherwise prohibited provided published from a bonafide scientific or social point of view. 4. Displayed signboards or notices by registered medical practitioners on his premises indicating that the treatment is undertaken for any disease, disorders or conditions specified in the schedule to this Act or in the rules made under this Act. 5. Advertisements relating to the drugs which comply with the required conditions as follows: (a) Leaflets or literature along with packing of drugs; or advertisements of drugs in medicinal,pharmaceutical, scientific and technical journals (b) Therapeutic index or price list published by licensed manufacturer, importer or distributor of drugs or medical literature distributed by medical representatives. With conditions that: i) The advertisement should contain only the information required for the guidance of registered medical practitioner regarding: (a) therapeutic indications; (b) route of administration; (c) dosage and side effects of such drug or drugs; and (d) the precautions to be taken in treatment with the drug ii) The distribution of such literature should be given to registered medical practitioners, dispensaries, hospitals, medical and research institutions, chemists and druggists or pharmacies.	**3**
2	b)	**Explain the BCS System of classification.** **Marking scheme - 3M** **Answer:** The biopharmaceutics classification system is a system to differentiate the drugs on the basis of their solubility and permeability.	**3**

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Q. No.	Sub No.	Answers	Marking Scheme
		BCS Classes: **Class I –High permeability, high solubility** i)Those compounds are well absorbed and their absorption rate is usually higher than excreation. ii)Example:Metoprolol, paracetamol. **Class II- high permeability, low solubility** i)The bioavailability of those products is limited by their solvation rate.A correlation between the in vivo bioavailability and in vitro solvation can be found. ii)Example :Glibenclamide, bicalutamide, ezetimibe, aceclofenac **Class III- Low permeability, high solubility** i)The absorption is limited by the permeation rate but the drug is solvated very fast.If the formulation does not change the permeability or gastro-intestinal duration time,than class I criteria can be applied. ii)Example:Cimetidine **Class IV- Low permeability, low solubility** i) Those compounds have a poor bioavailability. Usually they are not well absorbed over the intestinal mucosa and a high variability is expected ii)Example :Bifonazole.	
2	**c)**	**Give general principles of law** **Marking scheme: Any three principles- 3M** **Answer: The various general principles of law are-** **1. Supremacy of law** Supremacy of law means that the law has authority over all people, including those who administer the law. Dicey believes that a man should only be punished for a specific violation of the law, and not for anything else. The person cannot be punished by the Government solely on its own authority, but only in accordance with established law. **2. Equality before law** It means all people must be treated equally under the law. It ensures that everyone is treated equally before the law. It prohibits discrimination on various grounds, and treats everyone as equal in public employment. Also, it abolishes untouchability and titles. **3. Predominance of Legal Spirit** The spirit of justice is referred to as the legal spirit. For the effective implementation of rules of laws there should be impartial and independent judicial authority. According to Dicey, such authority will be court. This concept advocates the principle that law should be based on justice and interpreted without discrimination. **4. Principle of justice** The principle of justice obliges us to equitably distribute benefits, risks, costs, andresources. The following rules are supported by the principle of justice: 1. To each person an equal share 2. To each person according to need	**3**

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Q. No.	Sub No.	Answers	Marking Scheme
		3. To each person according to effort 4. To each person according to contribution 5. To each person according to merit. **5. Principle of liberty** According to John Stuart Mill every person has right to exercise his power in the community and act as per his will to prevent harm to others. An earlier equivalent was stated in France's Declaration of the Rights of Man and of the Citizen.	
2	**d)**	**What are the powers of Drug Inspector as per D&C Act,1940** **Marking scheme: 3M (Any 6 powers)** **Answer: Powers of Drug Inspector** Within the local limits for which the Inspector is appointed, he may, **i)Inspect:** 1) Any premises wherein any drug or cosmetic is being manufactured. And also he may inspect the means employed for standardizing and testing the drug or cosmetic. 2) Any premises wherein any drug or cosmetic is being sold or stocked or exhibited or offered for sale or distributed. **ii)Take samples of any drug or cosmetic** 1) Which is being manufactured or being sold or is stocked or offered for sale or exhibited or being distributed. 2) From any person conveying, delivering or preparing to deliver any drug or cosmetic to a purchaser or a consignee. **iii) Search** any person in connection with the offence under this chapter at all reasonable times. **iv) Enter and search** at all reasonable times, any place or premises in which he has reason to believe that an offence is being committed or has been committed. **v) Stop and search** any vehicle or other conveyance which he has reason to believe used for carrying any drug or cosmetic in respect of which offence has been or is being committed. **vi) Give order** in writing to the person in possession of drug or cosmetic in respect of which offence has been committed or is being committed, not to dispose stock of such drug or cosmetic for a specified period not exceeding twenty days or unless the defect may be removed by the possessor of the drug or cosmetic, and may seize the stock of such drug or cosmetic or any substance or article used to carry drug. **vii)Examine** any record, register, document or any other material object found while exercising above powers and seize the same if he has reason to believe that it is evidence of the commission of an offence under the Act. **viii) Exercise** any other powers as may be necessary, for carrying out the purpose of this Act and the rules thereunder.	**3**
2	**e)**	**Discuss certain operations controlled by the Central Govt. under NDPS Act,1985** **Marking scheme: 3M (Any 6 operations)** **Answer:** i) Government shall fix from time to time the limits within which licences may be given for the cultivation of opium poppy.	**3**

Q. No.	Sub No.	Answers	Marking Scheme
		ii) All opium, the product of land cultivated with the opium poppy shall be delivered by the cultivators to the officers authorized on behalf of the Central Government. iii) The Central Government may from time to time fix the price to be paid to the cultivators from the opium delivered. iv) The rules may prescribe the forms and conditions of licences or permits for the manufacture,possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances. The rules may also prescribe the authorities granted and the fees that may be charged therefor. v) The rules may prescribe the forms and conditions of licences for cultivation of the opium poppy and for the production and manufacture of opium. The rules may also prescribe the fees that may be charged therefore the authorities by which such licences may be granted, withheld,refused or cancelled and the authorities before which appeal against the orders of withholding,refusal or cancellation of licences shall lie. vi) The rules may prescribe that opium shall be weighed, examined and classified according to its quality and consistency by the officers authorized on this behalf by the Central government in the presence of the cultivator at the time of delivery by the cultivator. vii) The rules may provide for the weighment, examination and classification according to the quality and consistency of the opium received at the factory and the deductions from or addition to the standard price to be made in accordance with the result of such examinations.	
2	**f)**	**Discuss the qualification of Government Analyst.** **Marking scheme: 3M** **Answer: Qualifications of Government Analyst** A person to be appointed as Government Analyst should possess the following qualifications- (i) A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized University, with not less than 5 years post graduate experience in the testing of drugs; or (ii) A postgraduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university with not less than 3 years post graduate experience in the testing of drugs. or (iii) Associateship Diploma of the Institution of Chemists with 'Analysis of Drugs & Pharmaceuticals 'as one of the subjects with not less than 3 years experience in the testing of drugs in a laboratory under the control of - -A Government Analyst; or -Head of an Institution or - Testing laboratories approved for the purpose by appointing authority	**3**

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Q. No.	Sub No.	Answers	Marking Scheme
2	g)	**Discuss documentation, licenses and renewal procedure in Hospital pharmacy** **Marking Scheme: Documentation-1M, Licenses- 1M, Renewal- 1M** **Answer: 1) Documentation (1M)** 1. Statutory documents such as regulatory licenses, registrations, permissions, etc.) for operating a pharmacy´ 2. Operational documents, such as purchase invoices, sales invoices, 3. Other necessary documents such as Protocols (ii) Standard Working Procedures (iii) Operation instructions (iv) Quality Manual (v) Cleaning and maintenance records (vi) Complaint records (vii) Audit records(internal and external) (viii) Policy documents (ix) Personal documents: (i) Patients' health profile (ii) Patients' medication records (iii) Records of counselling follow-ups, etc. 4. Record of prescriptions. Prescription must contain-patient's name, age, sex, address, and institution/hospital along with its strength (especially in pediatrics age group), its dose frequency, duration in days, and total quantity (number of tablets and capsules). Laboratory investigation reports 6. Referral Notes: Always keep the carbon copy of referral note especially in case of critically ill patient. Referral note should mention the date and time of writing the note. Also write the treatment given. 7. Discharge Card: It shows the condition of the patient on the admission, investigation done, the treatment given and detail advice on discharge should be written on discharge card. 8. Copies of medical certificates issued as written evidence and accepted in court of if required **2) Licences (1M)** For the manufacture of following classes of drugs he should obtain the licences in the following forms a. Grant of a licence to manufacture drugs other than those specified in schedule C, C1, and X- Form 20 b. Grant of a licence to manufacture drugs specified in schedule C, C1, excluding those specified in schedule X- Form 21 b. Grant of a licence to manufacture for sale drugs specified in schedule X - Form 20 F 3**) Renewal of licences (1M)** For pharmacy in hospital as per retail sale. The granted licences are valid upto 5 years and should be renewed before expiry.	**3**

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Q. No.	Sub No.	Answers	Marking Scheme
		The licensee should apply to the licensing authority in the prescribed form accompanied with the prescribed fees. If If the licensee fails to pay license retention fee on or before the due date, he shall be liable to pay license retention fee along with a late fee, and in the event of non-payment of such fee, the license shall be deemed to have been cancelled.	
2	h)	**Define 'Misbranded drug' as per D & C Act,1940.** **Marking scheme: 3 M** **Answer: Misbranded drug** **Drug shall be deemed to be misbranded if –** i) it is so coloured, coated, powdered or polished that the damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or ii) it is not labelled in the prescribed manner; or iii) its label or container or anything accompanying drug bears any statement, design or devices which makes any false claim for drug or which is false or misleading in any particular.	**3**
2	i)	**Discuss the rules prescribed by the State Government in relation to possession and possession for sale of poison.** **Marking Scheme: Possession & sale of specified poisons: 2M (any 4 points) and 1M for Possession of any poison** **Answer: Possession & sale of specified poisons** The State Govt. may regulate the possession & sale of poison within the state. The sale may be wholesale or retail. The rules may be applicable for the whole or any part of the territories under the administration of the state.Such a rules may provide for: i) Grant of licenses for the possession of any specified poison for sale, either wholesale or retail. ii) Fixing of fees to be charged for such a licenses. iii) The classes of persons to whom the licenses for the possession & sale of poisons are to be granted. iv) The classes of persons to whom such poisons are to be sold. v) Maintenance of Register for the sale of poisons & inspection of the same. vi) Safe custody of poisons & the labelling of the vessel, coverings or packages in which such poison is sold or stored for sale. vii) Inspection & Examination of any such poison possessed for sale by any vendor. **Possession of any poison** State Government has power to make the rules regarding the possession of any specified poison in such local area where such poison may be used for murder or for poisoning cattle in such local area where such occurrences are very frequent.	**3**

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Q. No.	Sub No.	Answers	Marking Scheme
2	j)	**What are the functions of National Council for Clinical Establishment.** **Answer: Functions of National Council for Clinical Establishment** 1)Compile and publish a national register of clinical establishments within two years from the date of the commencement of this Act. 2)Classify the Clinical establishments into different categories. 3)Develop the minimum standards and their periodic review. 4)Determine within a period of two years from its establishment,the first set of standards for ensuring proper healthcare by the clinical establishments. 5)Collect the statistics in respect of clinical establishments. 6)Perform any other function determined by the Central Government from time to time.	3
2	k)	**Give bonafide reasons for termination of pregnancy under M.T.P.,1971.** **Marking Scheme: 3M** **Answer:** **1) Consent:-** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except: i) When the pregnant woman is less than 18 years of age or ii) The pregnant woman is lunatic. In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian. **2) Duration of pregnancies:** 1) A pregnancy may be terminated if it is not more than 12 weeks old & a medical practitioner is of the opinion that continuation of such pregnancy i) May involve a serious risk to the life of pregnant woman, & would result into serious injury to the physical or mental health of the pregnant woman, ii)The child to be born would be seriously handicapped due to physical or mental abnormalities. 2) A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old & not less than 2 RMPs are of the same opinion as above. 3) A pregnancy of any duration may be terminated by RMP when it 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 anymarried woman or her husband for the purpose of family planning	3

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Q. No.	Sub No.	Answers	Marking Scheme
3		**Attempt ALL of the following**	**20 M**
3	a)	**FSSAI stands for …….** **Answer**: Food Safety and Standards Authority of India	1
3	b)	**The HQ of CDSCO is located at …….** i) Mumbai ii) Delhi iii) Chennai iv) Kolkata **Answer**: ii) Delhi.	1
3	c)	**How often we donate blood?** i) After 24 hours ii) After 3 hours iii) After 3 months iv) After 6 months **Answer**: iii) After 3 months	1
3	d)	**…….. is celebrated as World Consumer Day**. i) 10 April ii) 15 March iii) 28 Feb iv) 1 Jan **Answer**: ii) 15 March	1
3	e)	**The full form of IAEC is……..** i) Institutional Animal Ethics Committee ii) Institutional Animal Ethics Corporation iii) Institutional Animal Education Committee iv) None of the above. **Answe**r: i) Institutional Animal Ethics Committee	1
3	f)	**Give a function of CPCSEA. (Any1 point)** **Answer:** (i) To regulate experimentation on animals. (ii) To regulate breeding and trade of animals for experimentation. (ii) Registration of establishments engaged in breeding and trade of animals, for experimentation. (iv) Registration of establishments conducting experiments on animals. (v) Constitution of Institutional Animals Ethics Committees (IAEC) of register establishments.	1

Q. No.	Sub No.	Answers	Marking Scheme
		(vi) Approval of animal house facilities. (vii) To approve research projects using large animals. (viii) To recommend on import of animals for experiments and breeding. (ix) To take appropriate action against establishments for violation of legal norms/stipulation. (x) To conduct and support a conference/workshop on animal ethics.	
3	g)	**Medical Device Class III stands for……** **Answer**: Moderate high risk	1
3	h)	**What does Schedule S prescribe under D & C Act 1940?** **Answe**r: Standards for Cosmetics	1
3	i)	**MTP Act was passed in a year.** **Answer**: 1971	1
3	j)	**The provisions of DPCO are implemented & enforced by …….** i) DPPA ii) NPPA iii) MAPE iv) None of the above **Answer**: ii) NPPA	1
3	k)	**Give the full form of NLEM.** A**nswe**r: National List of Essential Medicine (NLEM)	1
3	l)	**Give one function to the National Institute of Disaster Management**. **Answer:** i) Planning and promoting training and research in the area of disaster management. ii) Documentation of a national level information base relating to disaster management policies, prevention mechanisms and mitigation measures. iii) In addition, the institute performs various important functions, as regards to disaster management, specified under the Act.	1
3	m)	**Give functions of DTAB.** **Answer:** i) To advise the Central and State governments on technical matters arising out during administration of the D & C act. ii) To carry out the other function assigned to it under the D & C Act	1

WINTER– 2023 EXAMINATION

Model Answer – Only for the Use of RAC Assessors

Subject Name: **Pharmacy Law & Ethics** **Subject Code:** 20226

Q. No.	Sub No.	Answers	Marking Scheme
3	n)	**Pharmacist is liaison between ……..& ……..** **Answer**: Physician & Patient	1
3	o)	**Define Bioethics.** **Answer**: 'Bioethics is the study of ethical, social, and legal issues that arise in biomedicine and biological science. **OR** The discipline dealing with the ethical implications of biological research and applications especially in medicine.	1
3	p)	**For glass bottles, broken glass articles which bag is used as per Biomedical Waste Management Act?** **Answer**: Blue	1
3	q)	**State the long form of ICMR.** **Answer**: Indian Council of Medical Research	1
3	r)	**Enlist the principle of Bioethics.** **Answer:** 1. Principle of non-maleficence, 2. Principle of respect for autonomy, 3. Principle of beneficence, and 4. Principle of justice.	1
3	s)	**Indian Veterinary Research Institute is situated at ……** **Answer**: Izatnagar or Mukteshwar	1
3	t)	**What is good regulatory practice?** **Answer:** Good Regulatory Practices are recognized procedures, processes, systems & tools which improve quality & effective implementation of regulation. It provides sound, affordable & effective regulation of medical products & strengthens health care system.	1